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UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

ROBERT PEREZ, NANCY ART and BRETT HARBACH, on behalf of themselves and all others similarly situated,

Plaintiffs,

vs.

NIDEK CO. LTD.; NIDEK INCORPORATED; NIDEK TECHNOLOGIES INCORPORATED; MANOJ V. MOTWANI, M.D., GARY M. KAWESCH, M.D., LINDA VU, M.D., JOSEPH LEE, M.D., FARZAD YAGHOUTI, M.D., RANDA M. GARRANA, M.D., THOMAS S. TOOMA, M.D., PAUL C. LEE, M.D., KEITH LIANG, M.D., ANTOINE L. GARABET, M.D., WILLIAM ELLIS, M.D., GREGG FEINERMAN, M.D., MICHAEL ROSE, M.D., JOHN KOWNACKI, M.D., STEVEN MA, M.D., Estate of GLENN A. KAWESCH, M.D., TLC VISION CORPORATION also dba TLC LASER EYE CENTERS, INC.; CALIFORNIA CENTER FOR REFRACTIVE SURGERY, A MEDICAL CORPORATION; LASER EYE CENTER MEDICAL OFFICE INC.; SOUTHWEST EYE CARE CENTERS INC.; and DOES 1 through 1000, inclusive.

Defendants.

CASE NO. 3:08-CV-1261 BTM (JMA)

CLASS ACTION

SECOND AMENDED CLASS ACTION COMPLAINT FOR:

(1) VIOLATIONS OF HEALTH AND SAFETY CODE § 24176

(2) VIOLATIONS OF CIVIL CODE §1750, *ET SEQ*.;

(3-5) VIOLATIONS OF BUSINESS AND PROFESSIONS CODE § 17200, *ET SEQ*.; AND

(6) CIVIL CONSPIRACY

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Attorneys for Plaintiffs and the Class

Plaintiffs file this Class Action Complaint on behalf of themselves and all others similarly situated and by their attorneys allege upon information and belief the claims set forth herein against all defendants (collectively as "DEFENDANT PHYSICIANS & NIDEK"), based upon documentary evidence, the investigation of attorneys, the investigation of the Federal Food and Drug Administration("FDA"), and the federal Food, Drug, and Cosmetic Act ("the Act"), interviews and deposition transcripts of potential witnesses and persons knowledgeable of these events as follows:

I.

NATURE OF THE ACTION

1. This is a class action brought on behalf of persons who underwent Hyperopic (farsightedness) Laser in Situ Keratomilesis ("LASIK") and/or Hyperopic PhotoRefractive Keratectomy ("PRK") with a NIDEK EC-5000 Excimer Laser System ("the Laser") on or about February of 1996 until the date of October 11, 2006 ("the Class Period") who did not consent to and were not included in an approved FDA clinical trial.

2. During the Class period, the FDA had not approved the safety and effectiveness of the Laser to perform *hyperopic* corrections, i.e. the reduction or elimination of farsightedness. NIDEK had earned pre-market approval ("PMA") for three different parameters of *myopic* corrections, i.e. the reduction or elimination of nearsightedness. Nearsighted treatments involve simply flattening of the cornea similar to a strait blade cut across the cornea and thus easier to achieve (and consequently gain FDA approval for), while hyperopic corrections involve steepening the cornea which requires a more difficult doughnut shape cut of cornea tissue and thus was not attempted with the initial excimer eye lasers—nor approved by the FDA in any of the original excimer laser approvals.

3. At various times from the lasers original myopic (nearsightedness) approval in 1996 through its first hyperopic approval in October 2006, the laser was being investigated with various forms of hyperopic hardware and software under FDA approved clinical trials by both NIDEK and independent physician groups. Eventually in October 2006, the laser was approved for hyperopic use with improved and updated software and treatment parameters for hyperopic treatments, as opposed to what was used illegally by Defendant Physicians herein.

4. From its inception into the United States market in 1996, DEFENDANT

PHYSICIANS, NIDEK, and DOES 1-1000 engaged in a nationwide scheme and conspiracy to alter the laser's software and hardware to enable it to perform hyperopic corrections. Theses hyperopic corrections were not approved by the FDA absent the physician being involved one of the above-mentioned FDA approved hyperopic clinical trials. The Laser is considered by the FDA to be a Class III medical device under the Act; as such, the additional unapproved hardware and/or software (2.25 dhc software was never approved for commercial distribution in the United States) added to these Lasers makes them "adulterated" under the Act unless there is a PMA or an investigational device exemption (IDE) in effect for such hardware and software.

5. The California Protection of Human Subjects in Medical Experimentation Act provides minimum statutory protection for California patients with regard to human experimentation and provides penalties for those who violate such provisions. The law prohibits any person from being subjected to any medical experiment, until the person has given fully informed specific written consent. The law states: "Any person who is primarily responsible for conduct of a medical experiment and who negligently allows the experiment to be conducted without a subject's informed consent. . . shall be liable to the subject in an amount not to exceed ten thousand dollars($10,000), as determined by the court. The minimum amount of damages awarded shall be five hundred dollars ($500)". The law continues that one who willfully fails to obtain the subject's informed consent . . . shall be liable to the subject in an amount not to exceed twenty-five thousand dollars ($25,000) as determined by the court. The minimum amount of damages awarded shall be one thousand dollars ($1,000).

6. The current penalties were increased in September 2003, the former law made such a person who willfully failed to obtain the Subject's informed consent liable to the subject for a maximum amount of $5,000 and $10,000 for willful violations which "exposes a Subject to a known substantial risk of serious injury. . . ." The Plaintiffs herein allege that Defendants negligently and/or willfully failed to obtain their informed consent and did in fact subject them to a known substantial risk of serious injury. The law further states that "Each and every medical experiment performed in violation of any provision of this chapter is a separate and actionable offense". § 24176 Health & Safety.aq. Thus, if a patient underwent hyperopic surgery on her left eye, followed by hyperopic

surgery on her right eye, without proper written consent and being included in a legitimate FDA clinical trial, the patient would be entitled to collect the statutory penalties for each surgery.

7. The conduct by DEFENDANT PHYSICIANS, NIDEK, and DOES 1-1000 is unlawful, unfair, and fraudulent, and therefore in violation of California's Unfair Business Practices and Consumer Legal Remedies Act. Yet, despite years of complaints and warnings by the FDA and the American Academy of Ophthalmology that such use of the Laser was unlawful, DEFENDANT PHYSICIANS continued to conspire with NIDEK, , DOES 1-1000 and their agents to distribute, sell, service, enable and use the Laser in domestic commerce with parameters that allowed for hyperopic corrections, which were outside the specifications of its PMA.

8. During the Class Period, Plaintiff s and members of the Class underwent Hyperopic LASIK and/or PRK with the unapproved and/or illegal Laser and did not consent to this unauthorized use and/or were not informed and/or included in an FDA approved clinical trial.

9. For these and several other reasons, this Court should declare that conduct by DEFENDANT PHYSICIANS, NIDEK, and DOES 1-1000 and their agents, violates the California Health and Safety Code, is fraudulent, negligent, constitutes a civil conspiracy, battery, and is unlawful within the meaning of the California's Unfair Business Practices and Consumer Legal Remedies Act. This Court should award statutory penalties according to the California Health and Safety Code, and full restitution of all funds to which Plaintiffs can claim an ownership interest received by DEFENDANT PHYSICIANS, NIDEK, and DOES 1-1000.

II.

THE PARTIES

A. PLAINTIFFS

10. Plaintiff Robert Perez is over 18 years of age and is a resident of the State of California and the County of San Diego. On August 15th and September 12th of 2002, ROBERT PEREZ underwent hyperopic LASIK surgery with the Nidek Laser to attempt to correct his far-sightedness. These unapproved surgeries were performed by Defendant Manoj Motwani, M.D. (herein referred to as "MOTWANI") in San Diego, California. ROBERT PEREZ did not discover an unapproved, illegal or unlawful laser had been used on him until October, 2007. ROBERT PEREZ was not included in

and did not consent to being included in an FDA clinical trial for the Nidek Laser. Plaintiff PEREZ saw an ophthalmologist on or about October, 2007, who advised him to consider speaking to an attorney because his history revealed he had hyperopia and had Lasik surgery performed by Defendant MOTWANI using the Laser that was not FDA approved. Prior to PEREZ's visit with the ophthalmologist, PEREZ had no knowledge or suspicion that an unlawful, illegal, or unapproved laser had been used on him. Further, the Defendant's fraudulently concealed their conspiracy and illegal use of the Laser on this and all Plaintiff's herein; their purpose of such concealment was to be able to sell, service, use and as such increase their financial profits by illegally using the laser on farsighted patients as oppose to its approved and authorized use of nearsighted patients only. Plaintiffs did not and could not have reasonably discovered this unauthorized and illegal use of the Lasers on them prior to their discovery in 2007 as mentioned above.

11. Plaintiff NANCY ART is over 18 years of age and is a resident of the State of California and the County of San Diego. Plaintiff BRETT HARBACH is the son of NANCY ART and is over 18 years of age and also a resident of the State of California and the County of San Diego. On September 28th of 2000, Both NANCY ART and BRETT HARBACH underwent hyperopic LASIK surgery with the Nidek Laser to attempt to correct their far-sightedness. Thereafter, on May 23, 2001 BRETT HARBACH underwent a further hyperopic surgery in his right eye. These unapproved surgeries were performed by Defendant GLENN A. KAWESCH, M.D. (sued herein as ESTATE OF GLENN A. KAWESCH herein referred to as "GLENN KAWESCH") in San Diego. NANCY ART and BRETT HARBACH did not discover an unapproved, illegal or unlawful laser had been used on her until approximately October, 2007. NANCY ART and BRETT HARBACH were not included in and did not consent to being included in an FDA clinical trial for the Nidek Laser. Plaintiff ART saw an optometrist on or about October, 2007, who advised her to consider speaking to an attorney because her history revealed she had hyperopia and had Lasik surgery performed by Defendant GLENN KAWESCH that was not FDA approved. Prior to ART's visit with the optometrist, ART had no knowledge or suspicion that an unlawful, illegal, or unapproved laser had been used on her, or that clinical trials for Hyperopia on the Nidek laser were being conducted. Plaintiff ART is the mother of Plaintiff HARBACH and was aware he had also underwent hyperopic Lasik surgery performed by

Defendant GLENN KAWESCH at the same time she had her surgery. On or about October, 2007, Plaintiff ART advised Plaintiff HARBACH of what she learned from her optometrist. Further, the Defendant's fraudulently concealed their conspiracy and illegal use of the Laser on this and all Plaintiff's herein; their purpose of such concealment was to be able to sell, service, use and as such increase their financial profits by illegally using the laser on farsighted patients as oppose to its approved and authorized use of nearsighted patients only. Plaintiffs did not and could not have reasonably discovered this unauthorized and illegal use of the Lasers on them prior to their discovery in 2007 as mentioned above.

B. DEFENDANTS

12. Defendant NIDEK CO., LTD. is a corporation organized and existing under the laws of Japan. The corporate office is located in Gamagori, Japan. Said defendant is, through its officers, agents, and employees, manufacturers the Laser for sale, distribution, lease, and service and is doing business in California with offices located in Fremont, California.

13. Defendant NIDEK INCORPORATED is a corporation organized and existing under the laws of the State of California and is a wholly owned subsidiary of NIDEK CO., LTD. Said defendant is, through its officers, agents, and employees, engages in, markets, sells, services, and commercially distributes the Laser. Said defendant is the largest ophthalmic equipment marketer in the world with sales and service located in Fremont, California. Said defendant sells and distributes laser systems and diagnostic equipment developed and manufactured by defendant NIDEK CO., LTD., for uses in ophthalmology, optometry, general surgery, gynecology and cosmetic dermatological surgery.

14. Defendant NIDEK TECHNOLOGIES INCORPORATED is/was a corporation organized and existing under the laws of California and. It is/was through its officers, agents, and employees were doing business in California with offices located in Pasadena, California. It is/was a wholly-owned subsidiary of NIDEK CO., LTD. (NIDEK CO., LTD., NIDEK INCORPORATED and NIDEK TECHNOLOGIES INCORPORATED is herein referred to collectively as "NIDEK".)

15. At all times herein mentioned, Defendant MANOJ V. MOTWANI, M.D., was a practicing physician, surgeon in the County of San Diego, State of California, duly licensed to practice medicine under the laws of the State of California.

16. At all times herein mentioned, Defendant GARY M. KAWESCH, M.D., was a practicing physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

17. At all times herein mentioned, Defendant LINDA VU, M.D., was a practicing physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

18. At all times herein mentioned, Defendant JOSEPH LEE, M.D., was a practicing physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

19. At all times herein mentioned, Defendant FARZAD YAGHOUTI, M.D., was a practicing physician, surgeon and ophthalmologist in the County of San Diego, State of California, duly licensed to practice medicine under the laws of the State of California.

20. At all times herein mentioned, Defendant RANDA M. GARRANA, M.D., was a practicing physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

21. At all times herein mentioned, Defendant THOMAS S. TOOMA, M.D., was a practicing physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

22. At all times herein mentioned, Defendant PAUL C. LEE, M.D., was a practicing physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

23. At all times herein mentioned, Defendant KEITH LIANG, M.D., was a practicing physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

24. At all times herein mentioned, Defendant ANTOINE L. GARABET, M.D., was a practicing physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

25. At all times herein mentioned, Defendant WILLIAM ELLIS, M.D., was a practicing

physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

26. At all times herein mentioned, Defendant GREGG FEINERMAN, MD., was a practicing physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

27. At all times herein mentioned, Defendant MICHAEL ROSE, M.D., was a practicing physician, surgeon and ophthalmologist in the State of California, duly licensed to practice medicine under the laws of the State of California.

28. At all times herein mentioned, Defendant JOHN KOWNACKI, M.D., was a practicing physician, surgeon and ophthalmologist in the County of San Diego, State of California, duly licensed to practice medicine under the laws of the State of California.

29. At all times herein mentioned, Defendant STEVEN MA, M.D., was a practicing physician, surgeon and ophthalmologist in the County of Los Angeles, State of California, duly licensed to practice medicine under the laws of the State of California.

30. At all times herein mentioned, Defendant GLENN A. KAWESCH, M.D., was a practicing physician, surgeon and ophthalmologist in the County of San Diego, State of California, duly licensed to practice medicine under the laws of the State of California. Defendant Glenn A. Kawesch has subsequently died and is sued herein as ESTATE OF GLENN A. KAWESCH, M.D.) Defendant GLENN A. KAWESCH, M.D.'s entire medical practice was subsequently purchased by his brother GARY M. KAWESCH, M.D., who is already a named defendant in this action for using his Nidek Lasers illegally on Plaintiffs in his Northern California offices.

31. Defendant, TLC VISION CORPORATION also dba and/or formerly dba TLC Laser Eye Centers, Inc. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11 and a person within the meaning of Business & Professions Code § 17201. TLC VISION CORPORATION also dba and/or formerly dba TLC Laser Eye Centers, Inc. also owns Nidek lasers that were used to perform the unauthorized procedures and/or employs one or more Defendant physicians and/or DOES who performed the unauthorized/illegal surgeries in California. TLC VISION CORPORATION also dba and/or formerly dba TLC Laser Eye Centers, Inc. is a foreign corporation

organized and existing under Canadian law, and maintaining its principal place of business in MISSISSAUGA, ONTARIO and incorporated in the jurisdiction of NEW BRUNSWICK, CANADA.

32. Defendant, CALIFORNIA CENTER FOR REFRACTIVE SURGERY, A MEDICAL CORPORATION is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11 and a person within the meaning of Business & Professions Code § 17201. CALIFORNIA CENTER FOR REFRACTIVE SURGERY, A MEDICAL CORPORATION also owns a Nidek laser or lasers that were used to perform the unauthorized procedures and/or employs a Defendant physician and/or DOES who performed the unauthorized/illegal surgeries in California. CALIFORNIA CENTER FOR REFRACTIVE SURGERY, A MEDICAL CORPORATION is a California corporation organized and existing under California law, and maintaining its principal place of business in California.

33. Defendant, LASER EYE CENTER MEDICAL OFFICE INC. is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11 and a person within the meaning of Business & Professions Code § 17201. LASER EYE CENTER MEDICAL OFFICE INC. also owns a Nidek laser or lasers that were used to perform the unauthorized procedures and/or employs a Defendant physician and/or DOES who performed the unauthorized/illegal surgeries. LASER EYE CENTER MEDICAL OFFICE INC. is a California corporation organized and existing under California law, and maintaining its principal place of business in California.

34. Defendant, SOUTHWEST EYE CARE CENTERS INC., is a person in the course of doing business within the meaning of Health & Safety Code § 25249.11 and a person within the meaning of Business & Professions Code § 17201. SOUTHWEST EYE CARE CENTERS INC. also owned a Nidek laser that was used to perform the unauthorized procedures and/or employed a Defendant physician or physicians and/or DOES who performed the unauthorized/illegal surgeries. SOUTHWEST EYE CARE CENTERS INC. is a California corporation organized and existing under California law, and maintaining its principal place of business in California.

35. The above Defendants represented and held themselves out to the public and to plaintiffs as being skilled, careful and diligent in the practice of the profession of medicine and surgery and are herein referred to as "DEFENDANT PHYSICIANS."

C. DOE DEFENDANTS

36. DOES 1-200, and each of them, are officers, employers, or agents of the defendants and/or entities owned or controlled by the defendants and/or individuals and/or entities that owned or controlled the laser with the illegal and/or unapproved software and/or individuals and/or entities that serviced, sold, enabled and/or installed the laser with the illegal and/or unapproved software. DOES 1-200 participated in the course of conduct that is the subject of this action as alleged herein.

37. DOES 101-200, and each of them, are "persons" which participated in the course of conduct that is the subject matter of this action as alleged herein.

38. DOES 201-1000, and each of them, are practicing "physicians," "surgeons," and/or "medical centers" that perform refractive surgeries and participated in as well as conspired with other defendants in the course of conduct that is the subject matter of this action as alleged herein.

39. Plaintiffs and members of the Class are informed and believe, and thereon allege, that at all times herein mentioned, each of the defendants was the agent, servant and employee of the remaining co-defendants, and as such was acting within the time, place, purpose, and scope of said employment and agency and each defendant has ratified, authorized, and approved the acts of his agents.

40. Except as described herein, plaintiffs are ignorant of the true names, capacities and nature and extent of participation in the course of conduct alleged herein of the persons sued as DOES 1-1000 inclusive, and therefore sue these defendants by such fictitious names. Plaintiffs will amend this complaint to allege the true names and capacities of the DOE defendants when ascertained.

D. CO-CONSPIRATORS

41. Various persons, individuals, partnerships, corporations, and associations, not named as defendants in this Complaint, have also participated as co-conspirators in the violations alleged herein and have performed acts and made statements in furtherance thereof.

III.

CLASS ACTION ALLEGATIONS

42. Plaintiffs bring this action on behalf of themselves and as representative parties on behalf of all members pursuant to Rule 23 of the Federal Rules of Civil Procedure. The class that

plaintiffs ROBERT PEREZ, NANCY ART and BRETT HARBACH seek to represent is composed of and defined as follows: All persons who underwent Hyperopic LASIK and/or PRK with the Nidek Laser that were not given proper written informed consent and included in an approved FDA clinical trial during the Class Period.

43. This action has been brought and may be maintained as a class action, pursuant to the provisions of Rules23(a) and (b)(3)of the Federal Rules of Civil Procedure because questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy in the following ways:

A. The Class is so numerous that the individual joinder of all members is impracticable under the circumstances of this case. While the exact number of class members is unknown to the plaintiffs at this time, it based upon the number of persons whom underwent Hyperopic LASIK and/or PRK with the Laser that were not given proper written informed consent and included in an approved FDA clinical trial during the Class Period. Plaintiffs believe the persons in the class are so numerous, consisting of thousands of individuals, that the disposition of their claims in a class action rather than in individual actions will benefit the parties and the court.

B. Common questions of law and fact exist as to all members of the Class and predominate over any questions which affect only individual members of the class. These common questions of law and fact include, without limitation:

(i) whether DEFENDANT PHYSICIANS, NIDEK and DOES 1-1000 violated The California Protection of Human Subjects in Medical Experimentation Act of the California Health and Safety Code § 24176 against plaintiffs and members of the Class;

(ii) whether DEFENDANT PHYSICIANS, NIDEK and DOES 1-1000 committed fraudulent acts and/or omissions against plaintiff and members of the Class;

(iii) whether DEFENDANT PHYSICIANS, NIDEK and DOES 1-1000 committed civil conspiracy against plaintiff and members of the Class;

(iv) whether DEFENDANT PHYSICIANS, NIDEK and DOES 1-1000 violated the Unfair Business Practices §17200 et seq.;

(v) whether the amount of additional revenues and profits obtained by DEFENDANT PHYSICIANS, NIDEK and DOES 1-1000, are attributable to their violations of the Unfair Business Practices §17200 et seq.;

C. The claims of plaintiffs are typical of, and not antagonistic to, the claims and interests of the members of the Class. Plaintiffs and all members of the Class sustained statutory and restitution damages arising out of DEFENDANT PHYSICIANS, NIDEK and DOES 1-1000 common course of conduct in violation of law as complained herein.

D. Plaintiffs ROBERT PEREZ, NANCY ART and BRETT HARBACH will fairly and adequately protect the interests of the Class. Plaintiffs paid for and underwent hyperopic LASIK and/or PRK with the unapproved and/or illegal Laser which was being investigated by the FDA for its safety and effectiveness to perform hyperopic treatments and did not give written consent to be included and were not included in an FDA clinical trial; they are entitled to statutory damages and damages for restitution and are adequate representatives of the Class as they have no interests which are adverse to the interests of absent class members. Plaintiffs ROBERT PEREZ, NANCY ART and BRETT HARBACH have retained competent counsel who have substantial experience and success in the prosecution of complex class actions and intend to vigorously prosecute this action.

E. A class action is superior to other available means for the fair and efficient adjudication of this controversy since individual joiner of all members of the Class is impracticable. Class action treatment will permit a large number of similarly situated person to prosecute their common claims in a single form simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. Furthermore, as the damages suffered by each individual member of the Class may be relatively small, the expenses and burden of individual litigation would make it difficult or impossible for individual members of the class to redress the wrongs done to them, while an important public interest will be served by addressing the matter as a class action. The cost to the court system of adjudication of such individual litigation would be substantial, individualized litigation would also present the potential for inconsistent of contradictory judgments.

F. There is no plain, speedy, or adequate remedy other than by maintenance of this class

action since plaintiffs have been informed and believes that the damage to each plaintiffs are relatively small in amounts to the regression of vision making it economically unfeasible to pursue remedies other than a class action. Consequently, there would be a failure of justice but for the maintenance of the present class action.

G. Plaintiffs ROBERT PEREZ, NANCY ART and BRETT HARBACH are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

IV.

JURISDICTION & VENUE

44. This Court has jurisdiction over the subject matter of this action. This is a civil action for statutory penalties and full restitution and/or disgorgement of all revenues, earnings, profits, compensation, and benefits obtained by DEFENDANT PHYSICIANS, NIDEK and DOES 1-1000 inclusive, as a result of their unlawful, acts alleged herein as prohibited by The federal Food, Drug and Cosmetic Act and thus, in violation of The California Protection of Human Subjects in Medical Experimentation Act and the California Unfair Business Practices Act. This Court also has diversity jurisdiction over this matter under the Class Action Fairness Act of 2005 in that the aggregate amount in controversy is over $5,000,000 and primary Defendant NIDEK CO. LTD. and Defendant TLC VISION CORPORATION also dba and/or formerly dba TLC Laser Eye Centers are foreign corporations, while the named Plaintiffs are California residents.

45. Venue is proper in this judicial district, as defendants committed many of the acts alleged herein and named Plaintiffs and many other class members reside in this District.

V.

FACTUAL ALLEGATIONS & BACKGROUND

46. All laser products manufactured are subject to the requirements of the federal Food, Drug, and Cosmetic Act (the "Act"). Excimer lasers are classified under 21 U.S.C. § 360e, 360c as Class III medical devices. The Act requires premarket approval ("PMA") as a condition before the manufacturer may sell or distribute the Laser into domestic commerce.

47. On December 17, 1998, NIDEK earned its first PMA for the Laser for PRK for *myopia*

(emphasis added), i.e. the reduction or elimination of nearsightedness in the low, moderate, or high ranges (-.75D to -13.0D) of refractive error. The FDA granted NIDEK the PMA based upon the following restrictions: the Laser would not be used to perform *hyperopic (emphasis added)* corrections, i.e. reduction of elimination of farsightedness. The labeling, promotion, and advertising was restricted to what the Laser was approved. The sale, distribution, service and use of this Laser is restricted to its approval. All promotion and advertising was to include its restrictions. Annual reports were to be submitted. Reports of any instances of tampering with the device were to be immediately submitted. Most importantly, NIDEK, and its agents, were not permitted to introduce the Laser into commerce for hyperopic corrections.

48. 48. In its approval order, the FDA warned NIDEK, and its agents, that failure to comply with the above conditions would invalidate its approval. Yet, despite these warnings, NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, continued to sell, distribute, service, and use the Lasers to perform unapproved hyperopic treatments and introduce the Laser into domestic commerce with hardware and software applications different from the devices PMA which enabled it to perform unapproved hyperopic treatments. Nidek had service contracts on the vast majority of the lasers they sold in the United States (these service contracts sold to physician owners during the time period for between $30,000 and $70,000 per year; the contracts included several service visits per year by Nidek technicians.) During the Class period, Nidek was well aware that the Defendant physicians and other DOE physicians were using the lasers to perform unauthorized hyperopic treatments. Nidek was aware of these facts since it was Nidek service technicians themselves that were installing, servicing and enabling the Lasers to perform the unauthorized hyperopic treatments.

49. On September 29, 1999, NIDEK, received another PMA by the FDA for the Laser for PRK for the reduction or elimination of myopia with astigmatism ranging in severity from -1.0D to -8.0D.

50. The FDA again granted NIDEK, the PMA based upon the same restrictions as their previous PMA which were applicable to NIDEK, its agents, as well as physicians, users, and purchasers: Most importantly, NIDEK, and its agents, were not permitted to use or introduce the Laser into commerce for hyperopic corrections.

51. In its approval order, the FDA again warned NIDEK, that failure to comply with the conditions would invalidate its approval; thereby commercial distribution of the Laser not in compliance was deemed unlawful. Yet, despite these warnings, as mentioned above, NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, continued to sell, distribute, service, and use the Lasers to perform unapproved hyperopic treatments. Further, the DEFENDANT PHYSICIANS, and other DOE physicians 201-1000 failed to obtain the proper written informed consent from Plaintiffs and members of the class relating to the FDA clinical trials for hyperopia.

52. On April 14, 2000, NIDEK, and its agents, earned another PMA from the FDA for the Laser for LASIK for myopia from -1.0D to -14.0D with or without astigmatism less than 4.0D.

53. The FDA granted NIDEK's PMA based again upon the same restrictions including that the Laser not be used for hyperopic corrections.

54. DEFENDANT PHYSICIANS, and other DOE physicians 201-1000 were using the lasers to perform unauthorized hyperopic treatments without giving patients proper informed written consent and/or including them in an FDA clinical trial.

55. In order for NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, to perform hyperopic corrections, the Laser were manipulated, tampered with, and/or adulterated with illegal hardware and software. Prior to adding the illegal specifications, NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000 knew it was illegal, conspired to manipulate, tamper, and adulterate the Laser against FDA protocol rendering the Laser illegal and/or unapproved by the FDA.

56. On December 20, 2000, the FDA sent defendant NIDEK a letter addressing illegal uses of the Laser. This letter spoke of "ease by which illegal chips may be replaced in previously distributed units, thereby enabling these devices for indications beyond which they have been cleared..." The FDA determined NIDEK, and its agents, and the physicians and their agents, were aware and/or using the Laser to perform hyperopic corrections for several months before reporting the situation to the FDA, contrary to what is required for its PMA. Moreover, the FDA addressed allegations that NIDEK employees have been providing the illegal chips to physicians. Specifically, the warning letter stated,

> "We understand you have begun to address the chip replacement issue by visiting laser sites under service contract with NIDEK, and have determined that a significant number

of those lasers have been tampered with and have been enabled for unapproved applications, such as hyperopia. We also understand you had been aware of this problem for several months before initially reporting it to the FDA, contrary to what is required as a condition of approval of your PMA."

"There have been allegations that NIDEK employees have been providing these chips, and we are aware that you have terminated at least one employee for providing this service..."

"FDA is growing increasingly concerned that illegal chips are too easily replaced in NIDEK units and replacement chips have become too widely available."

57. Thereafter, the FDA issued two sets of Warning Letters to physicians. On July 11, 2001, the first Warning Letter stated in part,

"During an inspection of your facility, our investigator determined that you are using an excimer laser system for refractive surgery, including enhancement procedures that utilize hyperopia. Nidek CO., LTD in Japan manufactured this laser in February 1996, prior to the approval of their premarket approval application for the EC-5000 excimer laser."

The letter further stated,

"Medical devices used by doctors in the course of their practice to treat patients are "marketed" and "held for sale" with the meaning of the Federal Food, Drug, and Cosmetic Act (the Act). An excimer laser is a class III device under section 513(f) of the Act, and as such is adulterated under section 501(f)(1)(B) of the Act unless there is a PMA or an investigational device exemption in effect for it. Although your laser has a long working distance arm installed by Nidek Co., Ltd, while it was in Canada, this laser still contains software version 2.2.5 dhc, which is a version, not approved for commercial distribution in the United States."

"This laser does not meet all of the specifications for approval of Nidek's PMA for the EC-5000 Excimer laser and is not considered to be covered by that PMA. Because an approved PMA or an approved IDE does not cover this laser, it is adulterated within the meaning of the Act. Therefore, you should not be using this laser to treat patients."

"It is unlawful to sell unapproved devices in domestic commerce or to export them...Continued use of your excimer lasers for which neither a PMA nor IDE is currently in effect, is unlawful."

58. On July 26, 2001, the FDA sent a second warning letter entitled "Revised Warning Letter" to physicians, which restated the information in the first Warning letter dated July 11, 2001 and added,

"Your modified NIDEK lasers also need to be certified as in compliance with the Federal laser product performance standard pursuant to 21 Code of Federal Regulations (C.F.R.) §1040.10(I)."

"Laser product manufactured after August 1, 1976, are subject to all of the applicable requirements of the Federal performance standard for laser products specified in 21 CFR §1040.10 and 1040.11 and for certifying the products pursuant to 21 C.F.R. §1010."

> "It is unlawful for manufacturers to introduce such products into commerce if they fail to comply with the standard or fail to submit reports as required by 21 C.F.R. §1002. Our records show that no laser product reports for your modified devices have been received by our office."

59. On December 3, 2001, the FDA published an Import Alert, which represented the Agency's current guidance to FDA field personnel regarding manufacturers' products. In the report, the FDA addressed the following problem,

> "The software and specifications for these devices [NIDEK EC-5000 Excimer Laser] differ from the devices under the approved PMAs. The software and specification differences, however, are not discernable from an outside inspection of the device. Most of the exported device also do not contain a counting device used to monitor the number of procedures, and the labeling on the exported devices differs from that of approved devices. These previously exported devices are considered to be adulterated under the Act if they are sold or offered for sale in domestic commerce."

60. Despite these actions by the NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, continued to sell, distribute, lease, use, service, and market the Lasers in the United States with the capacity to perform hyperopic procedures. Hyperopic procedures consist of 25% of the population, thereby rendering a great profit motive for NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, to ignored federal regulations and continue to sell, use, and service the Laser despite its illegal nature.

61. In early 2001, in conjunction with negotiations with the FDA, NIDEK obtained a PMA to modify the Laser and install a "lock out" or "block"feature on the laser. This action essentially authorized and enabled Nidek representatives to remove the illegal hyperopic hardware and software (2.25dhc) which had been installed on the majority of the laser in the United States and replace it with the approved myopic software 2.25e. However, although many of the Nidek service records thereafter indicated that such software had been removed, the truth is that Nidek continued to install, service and enable the lasers to use the illegal software and perform hyperopic corrections; while many NIDEK service records thereafter indicated that the laser had been brought within the approved standards with approved 2.25e software, such records were falsified by Nidek and many of the lasers thereafter continued to use the unapproved hyperopic 2.25dhc software and hardware to treat unsuspecting patients.

VI.

FIRST CAUSE OF ACTION

Violation of Human Subjects in Medical Experimentation Act (California Health and Safety Code §24176)

(Against All Defendants)

62. Plaintiffs and members of the Class repeat and reallege each of the preceding paragraphs as though fully set forth herein.

63. DEFENDANT PHYSICIANS and DOES 201-1000, engaged, as herein alleged, violated the California Health and Safety Code §24176, against Plaintiffs and members of the Class, while NIDEK and DOES 1-200 also engaged in direct violation of this law and a conspiracy to violate the above-mentioned Code in detriment to Plaintiffs and members of the Class.

64. The California Protection of Human Subjects in Medical Experimentation Act provides minimum statutory protection for California patients with regard to human experimentation and provides penalties for those who violate such provisions. The law prohibits any person from being subjected to any medical experiment, until the person has given fully informed specific written consent. The law states: "Any person who is primarily responsible for conduct of a medical experiment and who negligently allows the experiment to be conducted without a subject's informed consent. . . shall be liable to the subject in an amount not to exceed ten thousand dollars($10,000), as determined by the court. The minimum amount of damages awarded shall be five hundred dollars ($500)". The law continues that one who willfully fails to obtain the subject's informed consent . . . shall be liable to the subject in an amount not to exceed twenty-five thousand dollars ($25,000) as determined by the court. The minimum amount of damages awarded shall be one thousand dollars ($1,000).

65. The current penalties were increased in September 2003, the former law made such a person who willfully failed to obtain the Subject's informed consent liable to the subject for a maximum amount of $5,000 and $10,000 for willful violations which "exposes a Subject to a known substantial risk of serious injury. . . ." The Plaintiffs herein allege that Defendants willfully failed to obtain their informed consent and did in fact subject them to a known substantial risk of serious injury

by performing laser eye surgery on them with these unapproved, adulterated lasers without their informed consent. The law further states that "Each and every medical experiment performed in violation of any provision of this chapter is a separate and actionable offense". § 24176 Health & Safety. Thus, if a patient underwent hyperopic surgery on her left eye, followed by hyperopic surgery on her right eye, without proper written consent and being included in a legitimate FDA clinical trial, the patient would be entitled to collect the statutory penalties for each surgery.

66. The Code states that "informed consent" means the authorization given pursuant to Section 24175 to have a medical experiment performed after numerous conditions have been satisfied. This includes:

A. A written consent form signed and dated by the subject.

B. The subject is informed both verbally and within the written consent form, in nontechnical terms of facts of the proposed medical experiment, including, but not limited to:

(i) An explanation of the procedure and medical device to be utilized, including the purposes of devices.

(ii) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.

(iii) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.

(iv) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.

(v) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

(vi) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment or other income, regardless of when it is earned or expected to be earned.

(vii) Consent is voluntary and freely given by the human subject or the conservator or

guardian, or other representative, as specified by Section 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.

67. None of the above written warnings were given by Defendant's in this case to the Plaintiffs or any members of the class. Defendant's negligently and/or intentionally withheld these disclosures in an effort perform these illegal hyperopic procedures to increase their profits. Plaintiffs believe and herein allege that Defendants willfully failed to obtain their informed consent and did in fact subject them to a known substantial risk of serious injury; as such, they would be entitled to the heightened penalties under the Statute.

VI.

SECOND CAUSE OF ACTION

Unfair Or Deceptive Acts Or Practices In Violation Of California Civil Code Section 1750 *Et Seq.*

68. Plaintiffs and members of the Class repeat and reallege each of the preceding paragraphs as though fully set forth herein.

69. By their wrongful conduct as alleged herein, Defendants have created, engaged in, and/or participated in unfair practices, in violation of California Civil Code Section 1750 *et seq.*, the Consumers Legal Remedies Act.

70. Defendants have engaged in unfair or deceptive acts or practices intended to result in the sale of their goods and services in violation of California Civil Code Section 1770, including but not limited to:

A. Misrepresenting the source, sponsorship, approval, or certification of goods or services, in violation of Section 1770(a)(2); and

B. Representing that goods or services have sponsorship, approval, or characteristics which they do not have, in violation of Section 1770(a)(5).

71. Pursuant to Section 1780, Plaintiffs and the members of the Class seek to enjoin Defendants from engaging in their unfair practices as alleged herein.

VII.

THIRD CAUSE OF ACTION

Violations of Unfair Competition Law
(California Business and Professions Code §17200 et seq.)
Based Upon Federal Food, Drug, and Cosmetics Act.

(Against All Defendants)

72. Plaintiffs and members of the Class repeat and reallege each of the preceding paragraphs as though fully set forth herein.

73. Business practices in which all defendants, NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, engaged, as herein alleged, constitute unlawful, unfair, and fraudulent business practices in violation of Business and Professions Code §17200 et seq. A violation of any underlying federal and/or state law effects a violation of Business and Professions Code §17200 et seq.

74. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, profited from their unfair business practices. Defendant's failure to comply with federal and state regulations increased the sales of the Lasers, thereby creating a greater profit for NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000.

75. Actions filed under Business and Professions Code §17200 et seq. may be brought by any person acting for the interest of itself, its members, or the general public. Plaintiffs have standing to bring this action under California Business & Professions Code §17200 because they have suffered injury in fact and have lost money because of the Defendant's conduct.

76. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000 inclusive, violated the provisions of the Act, 21 U.S.C. §331, which provides that the following acts and causing thereof are hereby *prohibited (emphasis added)* in part:

> (a) The introduction or delivery for introduction into interstate commerce of any device that is adulterated or misbranded; (b) the adulteration or misbranding of any device in interstate commerce;(c) the receipt in interstate commerce of any device that is adulterated or misbranded and the delivery or proffered delivery thereof for pay; (k) the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a device if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being adulterated or misbranded.

77. As defined in part by the Act under 21 U.S.C. §§351(f)(1)(B), 360c(f), 360e(a), a Class

III medical device shall be deemed to be adulterated unless it has PMA or an investigational device exemption that is in effect.

78. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, adulterated the Laser by intentionally and/or negligently leasing, using, selling, distributing, and servicing the Laser and introducing it into commerce with parameters allowing for hyperopic corrections, servicing the Lasers to perform hyperopic corrections in violation of its PMA.

79. Because NIDEK violated the conditions of its PMA, the Laser is not considered to be covered by that PMA. The specifications for the Laser differ from the Lasers approved under its PMA. This violates 21 U.S.C. §331 (a)-(c), (k), because NIDEK permitted the use, sale, lease, service, of an adulterated laser, and introduced such laser into commerce.

80. The Act was intended to prevent this type of damage to the public; plaintiffs are members the Class for whose protection the statutes were adopted.

81. Said conduct by NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, has resulted in statutory violations of the Act and Code as mentioned and therefore constitutes unlawful and unfair business practices within the meaning of the Business and Professions Code §17200. The Act and H & S Code placed mandatory duties on defendants.

82. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000 received funds from Plaintiffs and members of the Class as a result of the aforementioned acts. Plaintiff and members of the Class paid DEFENDANT PHYSICIANS, their agents, other DOE physicians, and their agents as well as DOES 201 to 1000 to perform Lasik procedures on them. DEFENDANT PHYSICIANS, their agents, other DOE physicians, and their agents as well as DOES 201 to 1000 in turn used Plaintiffs and members of the Class' money to pay NIDEK and DOES 1-200 for the purchase of their lasers and for expensive ($30,000 to $70,000 per year) service and maintenance contracts on their illegal lasers. Pursuant to Business and Professions Code §17203, the plaintiffs and members of the class are entitled to restitution of the funds they have an ownership interest in from NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000. Pursuant to Code of Civil Procedure §1021.5, the plaintiffs are entitled to cost, including attorneys' fees, for prosecuting this action in the public interest.

VIII.

FOURTH CAUSE OF ACTION

Violations of Unfair Competition Law
(California Business and Professions Code 17200 et seq.)
Based Upon Federal Food and Drug Administration
Department of Health and Human Services.

(Against All Defendants)

83. Plaintiffs and members of the Class adopt this cause of action repeat and reallege each of the preceding paragraphs as though fully set forth herein. The claims asserted herein arise out of the same nucleus of operative facts as those alleged under the preceding Count.

84. Business practices in which NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, engaged, as herein alleged, constitute unlawful, unfair, and fraudulent business practices in violation of Business and Professions Code §17200, et seq. A violation of any underlying federal or state law effects a violation of Business and Professions Code §17200 et seq.

85. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, profited from their unfair business practices. NIDEK's failure to comply with federal regulations increased the sales of the Lasers, thereby creating a greater profit for NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, were able to sell, use, purvey, and profit from an increased use and sales volume of the Laser due to the fact that NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000 sold and/or distributed and/or serviced and/or enabled and/or introduced the Laser into domestic commerce with specifications different from the devices under the approved PMA rendering the Laser unlawful. Such Lasers are illegal and should not to be used to treat patients. Further, NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, failed to notify the FDA of these acts and/or that the Laser was being used for a procedure unapproved by the FDA rendering the Laser illegal.

86. Actions filed under Business and Professions Code §17200 et seq. may be brought by any person acting for the interest of itself, its members, or the general public. Plaintiffs have standing to bring this action under California Business & Professions Code §17200 because they have suffered injury in fact and have lost money because of the Defendant's conduct.

87. Under the FDA, all Laser products must be in accordance with 21 C.F.R. §1040.10(a), §1040.10, which provides:

> Manufacturers of Laser products shall provide or cause to be provided: (I) the modification of a Laser product, previously certified under §1010.2, by any person engaged in the business of manufacturing, assembling, or modifying Laser products shall be construed as manufacturing under the act if the modification affects any aspects of the product's performance or intended functions for which this section and §1040.11 have applicable requirement. The manufacture who performs such modification shall recertify and reidentify the product in accordance with the provisions of 21 C.F.R. §§ 1010.2, 1010.3.

88. As defined by the FDA and the implementing regulations thereto, NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, have failed to comply with recertification and reidentification standards, as they have engaged in modifying, assembling, manufacturing, as well as the selling, use, and distribution and service of the Laser enabling it to perform LASIK and/or PRK refractive surgeries for corrections beyond which they have been cleared. NIDEK failed to recertify and reidentify the Laser after its modification in violation of 21 C.F.R. §§1040.10(a), §1040.10.

89. Said conduct by NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, in violation of this section proximately caused plaintiffs and members of the Class to undergo LASIK surgery with an unapproved Laser, and an unlawful procedure as alleged above, and incorporated herein in full.

90. The FDA regulations are intended to prevent this type of damage to the public; plaintiffs and members of the Class are persons for whose protection the statute was adopted.

91. Said conduct by NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, has resulted in statutory violations of the Health and Safety Code and therefore constitutes unlawful and unfair business practices within the meaning of Business and Professions Code §17200. The FDA and the Department of Health and Human Services places mandatory duties upon defendants.

92. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000 received funds from Plaintiffs and members of the Class as a result of the aforementioned acts. Plaintiff and members of the Class paid DEFENDANT PHYSICIANS and DOES 201-1000 to perform Lasik procedures on them. DEFENDANT PHYSICIANS and DOES 201-1000 in turn used Plaintiffs and members of the Class' money to pay NIDEK and DOES 1-200 for the purchase of their lasers and for service and

maintenance contracts on their illegal lasers.

93. Pursuant to Business and Professions Code §17203, the plaintiffs and members of the class are entitled to restitution of the funds they have an ownership interest in from NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000.

94. Pursuant to Code of Civil Procedure §1021.5, plaintiffs and members of the Class are entitled to cost, including attorneys' fees, for prosecuting this action in the public interest.

IX.

FIFTH CAUSE OF ACTION

Violations of Unfair Competition Law
(California Business and Professions Code 17200 et seq.)
Based Upon California Health and Safety Code §24176

(Against All Defendants)

95. Plaintiffs and members of the Class adopt this cause of action repeat and reallege each of the preceding paragraphs as though fully set forth herein. The claims asserted herein arise out of the same nucleus of operative facts as those alleged under the preceding Count.

96. Business practices in which NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, engaged, as herein alleged, constitute unlawful, unfair, and fraudulent business practices in violation of Business and Professions Code §17200, et seq. A violation of any underlying federal or state law effects a violation of Business and Professions Code §17200 et seq.

97. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, profited from their unfair business practices. NIDEK's failure to comply with State regulations increased the sales and service contracts of the Lasers, thereby creating a greater profit for NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, were able to sell, use, purvey, and profit from an increased use and sales volume of the Laser due to the fact that NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000 ignored state and federal used the illegal and untested laser on unsuspecting customers (patients) or in other words, the plaintiffs and class.

98. Actions filed under Business and Professions Code §17200 et seq. may be brought by any person acting for the interest of itself, its members, or the general public. Plaintiffs have standing

to bring this action under California Business & Professions Code §17200 because they have suffered injury in fact and have lost money because of the Defendant's conduct.

99. As alleged in the First Cause of Action, Defendants also violated California Health and Safety Code §24176 which provides:

> "Any person who is primarily responsible for conduct of a medical experiment and who negligently allows the experiment to be conducted without a subject's informed consent. . . shall be liable to the subject in an amount not to exceed ten thousand dollars($10,000), as determined by the court. The minimum amount of damages awarded shall be five hundred dollars ($500)". The law continues that one who willfully fails to obtain the subject's informed consent . . . shall be liable to the subject in an amount not to exceed twenty-five thousand dollars ($25,000) as determined by the court. The minimum amount of damages awarded shall be one thousand dollars ($1,000). The current penalties were increased in September 2003, the former law made such a person who willfully failed to obtain the Subject's informed consent liable to the subject for a maximum amount of $5,000 and $10,000 for willful violations which "exposes a Subject to a known substantial risk of serious injury. . . ."

100. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, have failed to comply with the informed consent requirements outlined above.

101. Said conduct by NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, in violation of this section proximately caused plaintiffs and members of the Class to undergo LASIK surgery with an unapproved Laser, and an unlawful procedure as alleged above, and incorporated herein in full.

102. The State regulations are intended to prevent this type of damage to the public; plaintiffs and members of the Class are persons for whose protection the statute was adopted.

103. Said conduct by NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, has resulted in statutory violations of the Health and Safety Code and therefore constitutes unlawful and unfair business practices within the meaning of Business and Professions Code §17200. The FDA and the Department of Health and Human Services places mandatory duties upon defendants.

104. NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000 received funds from Plaintiffs and members of the Class as a result of the aforementioned acts. Plaintiff and members of the Class paid DEFENDANT PHYSICIANS and DOES 201-1000 to perform Lasik procedures on them. DEFENDANT PHYSICIANS and DOES 201-1000 in turn used Plaintiffs and members of the Class' money to pay NIDEK and DOES 1-200 for the purchase of their lasers and for service and

maintenance contracts on their illegal lasers.

105. Pursuant to Business and Professions Code §17203, the plaintiffs and members of the class are entitled to restitution of the funds they have an ownership interest in from NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000.

106. Pursuant to Code of Civil Procedure §1021.5, plaintiffs and members of the Class are entitled to cost, including attorneys' fees, for prosecuting this action in the public interest.

X.

SIXTH CAUSE OF ACTION

Civil Conspiracy

(Against All Defendants)

107. Plaintiffs and members of the Class repeat and reallege each of the preceding paragraphs as though fully set forth herein.

108. Defendants NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, were aware of the federal and state standards regarding the Laser, knew that the Laser was in violation of the standards, and that the Laser was unlawful and/or illegal to use on patients.

109. Defendants NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, owed a duty to plaintiffs and members of the Class adopting this cause of action to give Plaintiffs and members of the class proper informed consent of the clinical trials and disclose to plaintiffs and members of the Class notice prior to undergoing refractive surgery that the surgery would be performed with an unapproved and/or illegal Laser. Given the nature of the activities in which defendants engaged, they had a heightened duty to undertake no acts that would endanger the public at large.

110. Defendants NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, knowingly and willfully conspired and agreed among themselves to withhold from governmental authorities and plaintiffs and members of the Class their knowledge that the Laser is illegal and/or unlawful.

111. Defendants NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, knowingly and willfully conspired and agreed among themselves to continue treating plaintiffs and

members of the Class with the illegal and/or unlawful Laser and to not give them proper informed consent as required by the Act and the Health and Safety Code.

112. Defendants NIDEK, and DOES 1-200, inclusive, knew that the plaintiffs were exposed and treated on by an unlawful and/or illegal Laser as a result of their and other defendants conduct.

113. Defendants NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, knew at all relevant times that plaintiffs and the class relied upon the Laser to be safe, effective, and approved by the FDA.

114. Defendants DEFENDANT PHYSICIANS and DOES 201-1000, inclusive, had a duty, as described herein, to cease treating plaintiffs and members of the Class with the Laser knowingly that it is illegal and/or unlawful.

115. Defendants NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, knowingly, intentionally conspired and agreed amongst themselves to misrepresent the safety and efficacy of the Laser.

116. Defendants NIDEK, DEFENDANT PHYSICIANS and DOES 1-1000, inclusive, committed the acts and/or omissions herein alleged pursuant to, and in furtherance of, the conspiracy of above-alleged agreement.

117. All defendants' conspiracy to suppress the information herein alleged was made with the fraudulent intent to induce plaintiffs to act in reliance thereon, and undergo refractive surgery without knowing the Laser was in fact unlawful and/or illegal, and as a result, all defendants NIDEK and DOES 1-200 were able to sell and service more Lasers to DEFENDANT PHYSICIANS and DOES 201-1000, of which were able to perform more operations and all defendants increased their profits.

118. Plaintiffs and members of the Class are informed and believe and thereon allege that the above-described conspiracy has existed since 1996 and that the conspiracy continued throughout the class period.

119. Pursuant to Code of Civil Procedure §1021.5, the plaintiffs and members of the Class are entitled to cost, including attorneys' fees, for prosecuting this action in the public interest.

XI.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and members of the Class pray for judgment as follows:

AS TO ALL CAUSES OF ACTION:

(Against All Defendants)

1. That this Court determine that this action may be maintained as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, on behalf of the Class, designating Plaintiff ROBERT PEREZ, NANCY ART and BRETT HARBACH as Lead Plaintiffs and Plaintiffs' counsel as Lead Counsel, and certifying the Plaintiffs ROBERT PEREZ, NANCY ART and BRETT HARBACH as proper class representatives;

2. For costs of suits herein, including reasonable attorney's fees for prosecuting this action in the public interest;

3. That plaintiffs and the other members of the Class be granted other and further relief as the nature of the case may require or this court deems just or proper.

AS TO THE FIRST CAUSE OF ACTION:

(Against All Defendants)

1. That Defendants be found to have failed to obtain each Plaintiff and each member of the Class's informed consent in violation of §24176 of the California Health and Safety Code;

2. That Defendants be ordered to pay each plaintiff and each member of the Class the maximum penalty pursuant to California Health and Safety Code §24176;

AS TO THE SECOND CAUSE OF ACTION:

(Against All Defendants)

1. That the Court permanently enjoin Defendants from engaging in the illegal conduct alleged in this Complaint;

AS TO THE THIRD THROUGH FIFTH CAUSES OF ACTION:

(Against All Defendants)

1. That Defendants be found to have engaged in unlawful, unfair, and fraudulent competition in violation of §17200 of the California Business and Professions Code;

2. That the Court order Defendants to disgorge all monies wrongfully obtained and all revenues and profits derived by Defendants as a result of their acts or practices as alleged in this Complaint;

3. That Defendants be ordered to make restitution to each plaintiff and each member of the Class pursuant to California Business and Professions Code §§17203 and 17204;

AS TO THE SIXTH CAUSE OF ACTION:

(Against All Defendants)

1. That Defendants be found to have engaged in a civil conspiracy to defraud Plaintiffs and the class of plaintiffs;

2. That the Court order Defendants to disgorge all monies wrongfully obtained and all revenues and profits derived by Defendants as a result of their acts or practices as alleged in this Complaint;

3. That the Court order Defendants to pay restitution to restore to all affected persons all funds acquired by means of any act or practice declared by this Court to be an unlawful, unfair or fraudulent act.

AS TO THE FIRST THROUGH SIXTH CAUSES OF ACTION:

(Against NIDEK and DOES 1-200)

1. Defendants NIDEK and DOES 1-200 acted with deliberate and/or reckless disregard for the rights of the Plaintiffs and the class. These acts were willful and/or wanton or reckless for their own self-interest. Defendants should also be held liable for punitive damages.

2. Further, Plaintiffs will bring a motion at the appropriate time seeking punitive damages against Defendant Physicians and DOES 201-1000 according to California Civil Code of Procedure section 425.13(a) which provides:

> In any action for damages arising out of the professional negligence of a health care provider, no claim for punitive damages shall be included in a complaint or other pleading unless the court enters an order allowing an amended pleadings that includes a claim for punitive damages to be filed. The court may allow the filing of an amended pleading claiming punitive damages on a motion by the party seeking the amended pleading and on the basis of the supporting and opposing affidavits presented that the plaintiff has established that there is a substantial probability that the plaintiff will prevail on the claim pursuant to Section 3294 of the Civil Code.

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Dated: October 7, 2008

Respectfully submitted:

By: /s Duane A. Admire
Duane A. Admire
Attorney for Plaintiffs
Robert Perez, Nancy Art & Brett Harbach