AUG 24 2005

# SUMMARY OF SAFETY AND EFFECTIVENESS
# NIDEK INCORPORATED OPD-STATION SOFTWARE

## SUBMITTER INFORMATION

| | | |
|---|---|---|
| A. | Company Name: | Nidek Incorporated |
| B. | Company Address: | 47651 Westinghouse Drive.<br>Fremont, CA 94539-7474 |
| C. | Company Phone:<br>Company Fax: | (510) 353-7719<br>(510) 226-5750 |
| D. | Contact Person: | Mr. Hiro Matsuzaki<br>Regulatory and QA Manager<br>Nidek Incorporated |
| E. | Date Summary Prepared: | August 22, 2005 |

## DEVICE IDENTIFICATION

| | | |
|---|---|---|
| A. | Generic Device Name: | Ophthalmic, aberrometer<br>Topographer, corneal, ac-powered |
| B. | Trade/Proprietary Name: | OPD-Station software |
| C. | Classification: | Class I 886.1760 |
| D. | Product Code: | NCF, MMQ |

## SUBSTANTIAL EQUIVALENCE

The Nidek Incorporated OPD-Station software is of comparable type and is substantially equivalent to the following predicate devices:

| Predicate Device | Manufacturer | 510(k) No. | Date Cleared |
|---|---|---|---|
| Topographic Modeling System | Computed Anatomy | K944207 | Dec. 7, 1994 |
| Nidek OPD-Scan | Nidek Co. Ltd. | K003299 | March 9, 2001 |

## DEVICE DESCRIPTION

Nidek has developed a stand-alone software option for users of the OPD-Scan™ device called OPD-Station, which will run on an independent PC (i.e., separate from the OPD-Scan™ device). The OPD-Station software is able to access data measured by the OPD-Scan™ device via a separate Nidek data management software package called NAVIS.

The OPD-Station uses the same software as that used for the OPD-Scan device so that a physician can view OPD-Scan data on their PC of choice. However, the OPD-Station software has the following new functions:

- Maps of Point Spread Function (PSF), Modulation Transfer Function (MTF), MTF graphing, and Visual Acuity mapping
- Improved color mapping

## INTENDED USE

The OPD-Station software is indicated for use in analyzing the corneal shape and refractive powers measured by the OPD-Scan Models ARK-9000 or ARK-10000, and to display the data in the form of maps, and manage the data.

## TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the OPD-Station software and the predicate devices has been performed, and the results of this comparison demonstrate that the OPD-Station software is equivalent to the marketed predicate devices

## PERFORMANCE DATA

The performance data indicate that the OPD-Station software meets all specified requirements, and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 4 2005

Nidek Co., Ltd.
% Ms. Carol L. Patterson, President
Patterson Consulting Group, Inc.
21911 Erie Lane
Lake Forest, CA 92630

Re: K050336
Trade/Device Name: OPD-Station Software
Regulation Number: 21 CFR 886.1760
Regulation Name: Ophthalmic Refractometer
Regulatory Class: Class I
Product Code: NCF, MMQ
Dated: July 15, 2005
Received: July 18, 2005

Dear Ms. Patterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# INDICATIONS FOR USE

510(k) Number: K050336 (To Be Assigned By FDA)

Device Trade Name: OPD-Station Software

Indications For Use: The OPD-Station software is indicated for use in analyzing the corneal shape and refractive powers measured by the OPD-Scan Models ARK-9000 or ARK-10000, and to display the data in the form of maps, and manage the data.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K050336

Concurrence of CDRH, Office of Device Evaluation (ODE)