SEP 3 0 2008

K082364

5. 510(k) Summary as required by 21 CFR 807.92(c)

510(k) Owner: Topcon Corporation.
75-1 Hasunuma-cho, Itabashi-ku
Tokyo, Japan 174

U.S. Facility:
Topcon Medical Systems, Inc.
37 West Century Road
Paramus, New Jersey 07652
Telephone: (201) 599-5153
Facsimile: (201) 599-5240

Contact person: Barbara S. Fant, Pharm.D.
Clinical Research Consultants, Inc.
310 Terrace Avenue
Suite 201
Cincinnati, OH 45220
Phone: (513) 961-8200
Facsimile: (513) 961-2858

Date: April 28, 2008

Trade Name: IMAGEnet Professional PC Software System

Common names: Digital Image Management Software
Digital Imaging Software for Retinal Cameras
Digital Imaging Software for Slit Lamps

Classification Name: Picture archiving and communications system
21 CFR 892.2050

Product Code: NFJ

Identification of a Legally Marketed Predicate Device

The IMAGEnet Professional PC Software System is substantially equivalent to the IMAGEnet Digital Ophthalmic Imaging System (v.2.12; IMAGEnet 2000) marketed by Topcon, 510(k) Premarket Notification Number K870039, FDA Product Code DSF. Secondly, it is substantially equivalent to the Nidek Advanced Vision Information System (NAVIS) marketed by Nidek Inc., 510(k) Premarket Notification Number: K013694, FDA Product Code NFJ.

General Description

The IMAGEnet Professional PC Software System is a computerized software system that collects, stores, and maintains images of the retina and anterior segment of the eye. The IMAGEnet Professional PC Software System is used together with retinal camera or digital camera imaging devices, including retinal cameras, non-mydriatic retinal cameras, and slit lamps. The IMAGEnet Professional PC Software System is installed in a Windows 2000 or Windows XP compatible PC to facilitate the functions of image capture, database archival of images, and image processing. The IMAGEnet Professional PC Software System has optional functions that may be selected to stitch a series of retinal images together or estimate the desired laser treatment size for photodynamic therapy (PDT). The Topcon IMAGEnet Professional PC Software System is intended as a software program for the use in the management of digital images acquired from diagnostic instruments that capture images of the retina and anterior segment of the eye.

Intended Use

The IMAGEnet Professional PC Software System is a software program that is intended for use in the collection, storage and management of digital images, patient data, diagnostic data and clinical information from computerized diagnostic imaging devices through direct connection with the instruments or through computerized networks.

Performance Data

Software validation testing and image capture testing were performed on the IMAGEnet Professional PC Software System. Test results for the IMAGEnet Professional Software System demonstrated sufficient agreement with captured images. The results of performance testing and software validation testing did not raise any issues on the safety or effectiveness of the device.

Basis of Substantial Equivalence

The IMAGEnet Professional PC Software System is substantially equivalent to the IMAGEnet Digital Ophthalmic Imaging System (v.2.12 IMAGEnet 2000) marketed by Topcon, 510(k) Premarket Notification Number K870039, FDA Product Code DSF, and regulation 21CFR§870.2810 (Recorder, paper chart) in software design and specifications, intended use, and compatible digital diagnostic equipment. Secondly, it is also substantially equivalent to the Nidek Advanced Vision Information System (NAVIS) marketed by Nidek Inc., 510(k) Premarket Notification Number: K013694, FDA Product Code NFJ, and regulation 21CFR§892.2050 (picture archiving and communications system) in basic design concept, in intended use, and use with similar digital diagnostic equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2008

Topcon Corporation
c/o Tamas Borsai, TUV Rheinland of North America
12 Commerce Road
Newton, CT 06470

Re: K082364
Trade/Device Name: IMAGEnet Professional PC Software System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: NFJ
Dated: September 15th, 2008
Received: September 18th, 2008

Dear Mr. Borsai:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

510(k) Number (if known): K082364

Device Name: IMAGEnet Professional PC Software System

Indications for Use:
The IMAGEnet Professional PC Software System is a software program that is intended for use in the collection, storage and management of digital images, patient data, diagnostic data and clinical information from computerized diagnostic imaging devices through direct connection with the instruments or through computerized networks.

The software system is indicated for use with retinal camera or digital camera imaging devices, including retinal cameras, non-mydriatic retinal cameras, and slit lamps.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises
510(k) Number K082364