K041367

NOV - 5 2004

TOPCON TRC-NW200 510(K) SUMMARY

Name of Device:	Topcon Model TRC-NW200 Non-Mydriatic Retinal Camera
Common / Generic Device Name:	Retinal Camera
Classification Name:	Camera, Ophthalmic, AC-Powered
Regulation Number:	886-1120
Product Code:	HKI
Submitter:	Topcon Corporation
Address:	37 West Century Road, Paramus, NJ 07652
Telephone Number:	(201) 261-9450
Facsimile Number:	(201) 387-2710
Contact Person:	Donald H. Winfield
Date Prepared:	August 12, 2004

Predicated Devices:

1)	Manufacturer:	Canon, Inc.
	Trade Name:	Canon
	Model Name:	CR6-45NM
	Classification Name:	86 HKI
	510(k) Number:	K 980246
2)	Manufacturer:	Canon, Inc.
	Trade Name:	Canon
	Model Name:	CR-DGi
	Classification Name:	86 HKI
	510(k) Number:	K 031629
3)	Manufacturer:	Nidek, Inc.
	Trade Name:	Nidek
	Model Name:	NM-1000
	Classification Name:	86 HKI
	510(k) Number:	K 014274

Description of Device:	The Topcon TRC-NW200 is a non-mydriatic ophthalmic camera that captures and displays images of the eye. The images are captured by using halogen illumination with an infrared filter for observation and a xenon flash bulb for photography. There is no laser illumination. Alignment dots and focusing bars assist the operator in properly positioning the camera. The operator presses a button on the top of the joystick to capture the image. The image is then displayed on the built-in LCD display or, if desired, transferred to a personal computer.
Intended Use:	Topcon Model TRC-NW200 Non-Mydriatic Camera is intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eyecare professional, without the use of a mydriatic.
Substantial Equivalence:	The TRC-NW200 and the predicated devices have the same intended use and indications. All of these devices are non-mydriatic ophthalmic cameras that capture and display images of the eye to aid the health care professional in diagnosing and/or monitoring diseases of the eye that may be observed and photographed. The NW200 and the predicated devices acquire these images according to the same principles of operation and technical characteristics. The question of safety and effectiveness is the same for the NW200 and the predicated devices. Therefore, the TRC-NW200 is substantially equivalent to legally marketed devices intended to capture images of the retina and the anterior segment of the eye and presenting this data to the eyecare professional without the use of a mydriatic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2004

Topcon Medical Systems, Inc.
c/o Donald Winfield
Vice President
37 West Century Road
Paramus, NJ 07652

Re: K041367
Trade/Device Name: Topcon Non -Mydriatic Retinal Camera, Model TRC-NW200
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: May 21, 2004
Received: May 24, 2004

Dear Mr. Winfield:

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) 594-4613. 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/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
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 (if Known): K041367

Device Name: Non-Mydriatic Retinal Camera, Model TRC-NW200

Indication for Use:

The Topcon Model TRC-NW200 Non-Mydriatic Camera is intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eyecare professional, without the use of a mydriatic.

Prescription Use ✓ 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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/05/2004

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

510(k) Number K041367