K130289

510(k) SUMMARY

MAY 10 2013

TOPCON TRC-NW8 Non-Mydriatic Retinal Camera

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Topcon Corporation
75-1 Hasunuma-Cho
Itabashi-Ku
Tokyo, Japan 174-8580
Phone: (201) 599-5553
Facsimile: (201) 599-5240
Contact Person: Michael Gusel

Additional Correspondent:

Maureen O'Connell
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864
Phone: (978) 207-1245
Facsimile: (978) 824-2541

Date Prepared: February 4, 2013

Name of Device and Name/Address of Sponsor

Topcon TRC-NW8 Non-Mydriatic Retinal Camera
Topcon Corporation
75-1 Hasunuma-Cho
Itabashi-Ku
Tokyo, Japan 174-8580

Common or Usual Name

Retinal Camera

Classification Name

Camera, Ophthalmic, AC-Powered
21 C.F.R. 886.1120
Product Code: HKI

Predicate Devices
Topcon Medical Systems TRC-NW8F (K100207)

Purpose of the Special 510(k) notice.
The TRC-NW8 is a modification to TRC-NW8F.

Intended Use
The TRC-NW8 is intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, with the use of a mydriatic or without the use of a mydriatic.

Device Description
This product is a retinal camera designed to observe, photograph or record the fundus oculi of a patient without coming into contact with the patient's eye and provide as an electronic image the obtained fundus oculi information for subsequent diagnosis. The TRC-NW8 can take both color photography and red-free photography. The TRC-NW8 is equipped with an observation monitor used for observation purpose and display of a photographed image. This product uses attached commercial digital single-lens reflex camera to photograph or record the fundus oculi of a patient. A photographed image may be recorded on a commercial memory card built into a commercial digital single-lens reflex camera or a personal computer (hereinafter referred to as a PC) or commercial memory devices (flash memories, hard disc, etc.). A commercial digital printer is connected and can print the observed images and the photographed images of the fundus.

Performance Data
The TRC-NW8 has been tested and found in compliance with the following recognized consensus standards:

IEC 60601-1:1988 +Amd 1: 1991 + Amd 2: 1995, Medical Electrical Equipment – Part 1: General Requirements for Safety;

IEC 60601-1-2: 2007 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance: Collateral Standard: Electromagnetic Capability – Requirements and Tests;

ISO 15004-1:2006 Ophthalmic Instruments-Fundamental requirements and test methods-Part 1: General requirements applicable to all ophthalmic instruments;

ISO 15004-2:2007, Ophthalmic Instruments-Fundamental requirements and test methods-Part 2: Light hazard protection.

Design verification tests were performed as a result of the risk analysis assessment. These test results demonstrated that the TRC-NW8 met predetermined acceptance criteria.

Substantial Equivalence

The TRC-NW8 has the same intended use, indications for use and principles of operation as the TRC-NW8F, to which it is a modification. The TRC-NW8 is identical to the TRC-NW8F with the following exceptions:

- The TRC-NW8F performs fluorescein angiography while the TRC-NW8 does not. The TRC-NW8F uses an exciter filter and a barrier filter which are not present in the TRC-NW8.

These modifications were evaluated by Topcon to determine if they could affect the safety or effectiveness of the device and it was determined that they do not. Verification and validation was performed to ensure that the device performs as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 10, 2013

Topcon Medical Systems, Inc.
% Ms. Maureen O'Connell
Regulatory Affairs and Quality Assurance Manager
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, MA 01864

Re: K130289
Trade Name: TRC-NW8 Non-Mydriatic Retinal Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: AC-Powered Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: April 9, 2013
Received: April 10, 2013

Dear Ms. O'Connell:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for 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

Indications for Use Statement

510(k) Number (if known): K130289

Device Name: TRC-NW8

Indications for Use:

The TRC-NW8 is intended for use in capturing images of the retina and the anterior segment of the eye and presenting the data to the eye care professional, with the use of a mydriatic or without the use of a mydriatic.

Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew Yang -S
2013.05.01
15:11:02 -04'00'

(Division Sign-Off)
Division of Ophthalmic, and
Ear, Nose, Throat Devices
510(k) Number: K130289