5. 510(k) SUMMARY

JUN 30 2009

510(k) Owner:

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Phone Number: +81-3-3558-2566
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Date: October 3, 2008

Trade Name: Retinal Camera TRC-NW7SF MARK II

Common names: Retinal Camera

Classification Name: Camera, Ophthalmic, AC-Powered
21CFR886.1120

Product Code: HKI

Intended Use / Indication for Use

The TOPCON Retinal Camera TRC-NW7SF MARK II 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 use of a mydriatic.
For details of Patient Profiles, please refer Attachment 16.

General 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.
This product comes in two types: a type that capable of both color photography and fluorescein angiography (hereinafter referred to as FA photography); and "Type IA" capable of color photography, FA photography and indocyanine green angiography (hereinafter referred to as IA photography).
This product is either equipped with or without an observation monitor used for observation purpose and display of a photographed image. This product comes in three types: a type that houses a digital photography unit for photographing an image; a type to which a commercial TV camera is attached; and a type to which a commercial digital single-lens reflex camera. A digital photography unit, a TV camera and a digital single-lens reflex camera are hereinafter generally referred to as an electronic photography device. A photographed image may be recorded on a commercial memory card built into an electronic photography device, or a connected commercial printer, or a personal computer (hereinafter referred to as a PC).
*Type IA is used as a catalog symbol.

Performance Data

The maximum exposure has been demonstrated to be well below the accepted threshold limits set out in ISO 15004-2:2007. (See Attachment 1)
The resolving power and the photographic angular field of view as defined in ISO 10940:1998 "Ophthalmic instruments -- Fundus cameras" have been measured and the result meet the requirement value set out in TOPCON self standards. (See Attachmet 2)
In all instances, the TOPCON Retinal Camera TRC-NW7SF MARK II functioned as intended.

Basis of Substantial Equivalence

The TOPCON Retinal Camera TRC-NW7SF MARK II is as safe and effective as Canon Inc. Fundus Camera CF-60UVi (K946058), TOPCON CORPORATION Non-Mydriatic Retinal Camera TRC-NW200 (K041367) and Kowa Company, Ltd. KOWA VX-10 (K043213). The TOPCON Retinal Camera TRC-NW7SF MARK II and the predicated devices have the same intended use and similar indications, technological characteristics, and principles of operation. The minor technological differences between the Retinal Camera TRC-NW7SF MARK II and its predicate devices raise no new issue of safety or effectiveness. Performance data demonstrate that the Retinal Camera TRC-NW7SF MARK II is as safe and effectiveness as required in applicable international standards such as ISO 15004-2:2007 and so on. Thus, the Retinal Camera TRC-NW7SF MARK II is substantially equivalent.

Standards for testing

TOPCON conducted several tests for the TOPCON Retinal Camera TRC-NW7SF MARK II to ascertain conformity to following standards.

IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991; Amendment 2, 1995
IEC 60601-1-2	Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004))
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

No deviation or adaptation is made in the use of above mentioned standards.
See Attachment 3 for IEC 60601-1 Test Reports and IEC 60601-1-2 Test Reports.
See Attachment 4 for ISO 15004-2:2007 Test Reports.
See Attachment 1 for ISO 15004-2:2007 Test Reports.
See Attachment14 for Form FDA 3654 of each standard.

The TOPCON Retinal Camera TRC-NW7SF MARK II has no component which contacts with blood, bodily fluid or mucous membrane. Therefore, Biocompatibility tests were not performed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 2009

Topcon Corp.
c/o Tamas Borsai
TÜV Rheinland of North America, Inc.
12 Commerce Rd.
Newton, Connecticut 06470
United States

Re: K090115
Trade/Device Name: Retina Camera TRC-NW7SF MARK II
Regulation Number: 21 CFR 886.1120
Regulation Name: Ophthalmic Camera
Regulatory Class: II
Product Code: HKI
Dated: June 16, 2009
Received: June 17, 2009

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
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): **K090115**

Device Name: **Retina Camera TRC-NW7SF MARK II**

Indications For Use:

Retina Camera TRC-NW7SF MARK II system 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 or without the use of mydriatic.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K090115