K123101

510(k) SUMMARY
Topcon Medical Systems, Inc.
TRC-50DX Retinal Camera

JUN 5 2013

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

Topcon Medical Systems, Inc.
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O'Connell Regulatory Consultants, Inc.
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Date Prepared: May 29, 2013

Name of Device and Name/Address of Sponsor

Topcon TRC-50DX Retinal Camera
Topcon Medical Systems, Inc.
111 Bauer Drive
Oakland, NJ 07436

Common or Usual Name

Retinal Camera

Classification Name

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

Predicate Devices

Topcon TRC-NW7SF Mark II Retinal Camera (K090115)
Canon CX1 (K092565)

Intended Use / Indications for Use

The TRC-50DX Retinal Camera 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.

Technological Characteristics

The Topcon TRC-50DX Retinal Camera is designed to observe, photograph and record the fundus oculi of a patient without coming into contact with the patient's eye and provide an electronic image of the fundus oculi information for subsequent diagnosis. The TRC-50DX is provided in several configurations based on the photography needs of the user.
The configurations are shown in following table.

TRC-50DX

Configuration	Digital Camera attachment		Digital Camera Body			Imaging Mode
			Nikon D90	Pike F-1100C	Stingray F-145B	
1	Main Body	Lower mount		√		Color, Red Free, FA
2	Relay Lens TL-211	Port1	√			Color, Red Free, FA
3	Main Body	Lower mount		√		Color
	Relay Lens TL-209	Port1			√	Red Free, FA, AF
4	Relay Lens TL-238D	Port1	√			Color
		Port2			√	Red Free, FA, AF

TRC-50DX Type IA

Configuration	Digital Camera attachment		Digital Camera Body			Imaging Mode
			Nikon D90	Pike F-1100C	Stingray F-145B	
3 Type IA	Main Body	Lower mount		√		Color
	Relay Lens TL-209	Port1			√	Red Free, FA, ICG, AF
4 Type IA	Relay Lens TL-238D	Port1	√			Color
		Port2			√	Red Free, FA, ICG, AF

The fundamental technical specifications of the Relay Lenses and Digital Cameras are shown in below.

Model	Type	Port and Mount		Size
TL-209	1 Port	Port 1	C Mount	85×140×236
TL-211	1 Port	Port 1	F Mount	85×140×236
TL-238D	2 Port	Port 1	F Mount	85×189×236
		Port 2	C Mount	

Digital Camera Body	Specification
Nikon D90	APS-C size CMOS single-lens reflex digital camera (Color) 12.3M pixels
Allied Pike F-100C	35mm CCD and single-plate digital camera (Color) 11M pixels
Allied Stingray F-145B	2/3 inch CCD single-plate digital camera (B/W) 1.4M pixels

Performance Testing

Software verification and validation, system performance testing, optical radiation safety hazard analysis (ISO 15004-1 and ISO 15004-2) and electrical safety and EMC testing (IEC 60601-1 and IEC 60601-1-2) have been performed to support the substantial equivalence of the TRC-50DX. Additionally performance testing which compares image quality with the TRC-50DX to the Topcon TRC-NWSF MARK II and Canon CX-1 was performed. Images were evaluated and graded by a masked examiner based on the following image quality factors: focus, illumination, field definition, artifact, small pupil artifact and media opacity. The study found the scores from the TRC-50DX images were similar to or better than the scores of the images from the predicate devices.

Substantial Equivalence

The Topcon TRC-50DX Retinal Camera is as safe and effective as the identified predicate devices including the Topcon TRC-NW7SF Mark II Retinal Camera (K090115) and the Canon CX-1 (K092565). The Topcon TRC-50DX Retinal Camera has the same intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicates. The Topcon TRC-50DX Retinal Camera is as safe and effective as its predicate devices, and thus, substantially equivalent.

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

June 5, 2013

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

Re: K123101
Trade/Device Name: TRC-50DX Retinal Camera
Regulation Number: 21 CFR 886.1120
Regulation Name: AC-Powered Ophthalmic Camera
Regulatory Class: Class II
Product Code: HKI
Dated: May 29, 2013
Received: May 30, 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 contact 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. 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

510(k) Number (if known): K123101

Device Name: Topcon TRC-50DX Retinal Camera

Indications For Use:

The TRC-50DX Retinal Camera is intended for use in capturing images of the retina and anterior segment of the eye and presenting the data to the eye care professional, with the use of a mydriatic.

Prescription Use___X_____ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number: K123101