K093624 ① of ②

510(k) Summary of Safety and Effectiveness
Optiscan Confocal Endoscopic Imaging System

MAR - 5 2010

Submitter Information:
Optiscan Pty Ltd
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Date Summary Prepared: 27 January 2010

Name of Device:

Trade Name:	Optiscan CEIS
Classification Name	Endoscope and Accessories (21CFR876.1500)
Product Code	GCJ, KOG

Predicated Device(s) Information:

Model, Description	Manufacturer	PMN #
Pentax Confocal Laser System	Pentax	K042740

Device Description:
The Optiscan Confocal Endoscopic Imaging System (CEIS) is a software controlled device which is intended for use as a required accessory with a legally marketed and compatible video endoscope system that is equipped with confocal imaging module.

The Confocal Endomicroscopy Imaging System (CEIS) consists of three main units.

1. The Control Unit (CEIS-CU) together with its monitor, keyboard, and footswitch, is a computer based unit which performs the instrument control, and image capture and processing functions of the CEIS.
2. The Optical Unit (CEIS-OU) a specialised endomicroscope interface unit which performs the laser illumination and fluorescence detection functions of the CEIS.
3. The Isolation Transformer.

A video endoscope equipped with a confocal imaging module is connected to the CEIS-OU. Under control by the endoscopist, the CEIS-OU transmits visible laser light into the connected endoscope. The endoscope transmits this light to and then subsequently receives return light signals from the subject tissue. The returned light is detected by the CEIS-OU and converted into an electrical signal. The detected signal is sent to the System Computer (CEIS-CU) which processes the confocal image information for display on the system monitor, and allows still images of the tissue to be captured and stored.

Intended Use:
The Confocal Endoscopic Imaging System (CEIS) is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Comparison to Predicated Device(s):
The submission for substantial equivalence included Optiscan Confocal Endoscopic Imaging System (CEIS) literature including intended use and specifications. Comparison tables were provided to illustrate the comparisons to the predicated devices for intended use, technical specifications and materials. The submission for substantial equivalence was not based on an assessment of clinical performance data.

Conclusion:
Because the Optiscan Confocal Endoscopic Imaging System (CEIS) possesses the same or similar intended use, indications, and technological characteristics as the identified predicate device, with no additional questions of safety or effectiveness, the company submits that the device can be found to be substantially equivalent.

Prepared By:

Peter Pavlicek
Quality and Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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MAR - 5 2010

TUV Rheinland of North America, Inc.
% OptiScan Pty. Ltd.
Mr. Peter Pavlicek
15-17 Normanby Road
Notting Hill, Victoria 3168
Australia

Re: K093624
Trade/Device Name: Optiscan CEIS
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 19, 2010
Received: February 24, 2010

Dear Ms. Pavlicek:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K093624

Indications for Use

510(k) Number (if known):

Device Name: Optiscan CEIS

Indications for Use:

The Confocal Endoscopic Imaging System (CEIS) is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by legally marketed video endoscopes (equipped with a confocal laser imaging module), during endoscopic medical examination procedures. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K093624