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

Pentax Medical Company
% Mr. Tamas Borsai
Division Manager, Medical Division, and
Program Manager, Third Party, Review Program
TÜV Rheinland of North America
12 Commerce Road
Newtown, CT 06470

JUL 27 2015

Re: K042740
Trade/Device Name: ISC-1000 Confocal Laser System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated (Date on orig SE ltr): September 30, 2004
Received (Date on orig SE ltr): October 4, 2004

Dear Mr. Borsai,

This letter corrects our substantially equivalent letter of October 19, 2004.

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,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K042740

Device Name: ISC-1000, Confocal Laser System

Intended Use Statement:

The Pentax confocal laser system is a required accessory for legally marketed video endoscopes equipped with a confocal laser imaging module. The system is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by the endoscope. The system is applied when indications consistent with the requirement for procedure are observed in adult and pediatric patient populations.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

Prescription Use (Per 21 CFR 801.109)

510(k) Number K042740

OCT 1 9 2004

K042740

510(k)Summary
Pentax Confocal Laser System

Submitter Information:

Pentax Medical Company
102 Chestnut Ridge Road
Montvale, New Jersey 07645-1856
Tel: (201)-391-0932

Name Of Device:

Trade Name:	Pentax Confocal Laser System
Classification Name:	Endoscope and Accessories (78KOG) {876.1500} [Class II]

Predicated Device(s) Information:

Model, Description	Manufacturer	PMN#
Zeiss Confocal Laser	Carl Zeiss, Inc.	K912581

Device Description:
The Pentax Confocal Laser System (software controlled device) is intended for use as a required accessory with Pentax video endoscope system that are equipped with confocal imaging module. The confocal laser system includes a laser light source, system computer, and display monitor. A video endoscope equipped with a confocal imaging module is connected to a conventional video endoscope system that will present the video endoscopic image. The endoscope is connected to the confocal system laser light source. The endoscope confocal imaging module contains an optical fiber that transmits laser light to, and receives return light from, the subject tissue. The confocal laser system contains a laser light source which produces visible laser light and contains signal detection circuitry to transmit/ receive the light signals through the endoscope confocal imaging module. The detected signal is sent to the system computer. The System Computer processes the confocal image information for display on the system monitor, controls the laser light source, and acts as an image storage device for still frame images.

Intended Use:
The Pentax confocal laser system is a required accessory for legally marketed video endoscopes equipped with a confocal laser imaging module. The system is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical track accessed by the endoscope. 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 Pentax Confocal laser system literature including specifications, the identification of standard set components, and identification of optional accessories, comparison tables were provided to illustrate the comparisons to the predicated devices. The submission for substantial equivalence was not based on an assessment of clinical performance data.

Prepared By:

Paul Silva

Paul Silva, Regulatory Affairs Coordinator

09-09-2004
Date