SEP - 6 2005

K051585

Mauna Kea Technologies

E.0 Premarket Notification 510(k) Summary

E.1 Submitter Information

Company Name and Address:

Mauna Kea Technologies
9, rue d'Enghien
75010 Paris
FRANCE

Contact Name:

Alexandre Loiseau, Ph.D. (Official Correspondent)
President
Mauna Kea Technologies
Telephone: +33 1 48 24 06 21
Fax: +33 1 48 24 12 18

Date Prepared: June 9, 2005 ; revised August 16, 2005

E.2 Name of Device

Proprietary Name: F-400 System

Classification Name: Endoscope and/or Accessories

E.3 Predicate Device(s) Information

Pentax Confocal Laser System, K042740

Pentax EC-3870CILK Confocal Video Colonoscope, K042741

superDimension Bronchus, K042438

K053553

Mauna Kea Technologies

E.4 Device Description

The F-400 system is a confocal microscope with a fiber optic probe which allows *in vivo* visual inspection of tissues with a microscopic resolution during an endoscopic procedure. The F-400 system has been designed to allow real-time observations of tissues. The device is based on a common laser scanning technology adapted for imaging through a bundle of optical fibers and is thus composed of several elements: a Laser Scanning Unit, proprietary software running on a remote computer, a medical grade flat panel display and Miniaturized Fiber Optic Probes. The F-400 system can be used with any legally marketed endoscope with a working channel of 2.8 mm or greater.

E.5 Intended Use

The Mauna Kea technologies F-400 system is a confocal laser imaging system that is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical tract, i.e., gastrointestinal or respiratory, accessed by the endoscope.

E.6 Comparison to Predicate Device(s)

The comparison to the predicate devices was based on a review of the F-400 system information included in the company's 510(k) Premarket Notification and information concerning the predicate devices that was available in the public domain. A product brochure for the Pentax Confocal Laser System, K042740, and Pentax EC-3870CILK Confocal Video Colonoscope, K042741 was reviewed and information for the superDimension / Bronchus was obtained from the superDimension web site, www.superdimension.com. Copies of reviewed information are included in the F-400 System 510(k) Premarket Notification. The comparison reviewed general technological considerations as well as specific performance parameters for all predicate devices where information was available. Neither animal nor clinical data were assessed.

Accepted scientific methods were followed to conduct non-clinical testing, i.e., design verification and validation and testing to recognized standards. The purpose of this testing served to evaluate whether safety or effectiveness had been adversely affected by technological differences between the F-400 system and the predicate devices.

Mauna Kea Technologies SAS
Société par actions simplifiée au capital de 163.157,34 Euros -
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Testing to FDA recognized standards was performed in the areas of electrical safety, electromagnetic compatibility, laser safety, endoscopic equipment, bioburden, soft-controlled medical devices, risk analysis, biocompatibility and packaging.

In conclusion, the data from the non-clinical testing, i.e., design verification and validation and testing to FDA recognized standards demonstrated that the F-400 system is as safe and effective as all of the above mentioned predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2005

Alexandre Loiseau, Ph.D.
President
Mauna Kea Technologies
9, rue d'Enghien
75010 Paris
France

Re: K051585
Trade/Device Name: F-400 System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: August 16, 2005
Received: August 17, 2005

Dear Dr. Loiseau:

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.

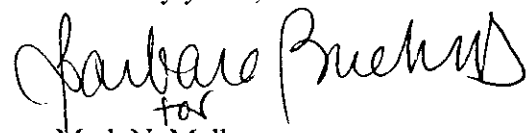
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

510(k) Number (if known): K# 051585

Device Name: F-400 System

Indications for Use:

The Mauna Kea Technologies F-400 System is a confocal laser imaging system with fiber optic probes that is intended to allow confocal laser imaging of the internal microstructure of tissues in the anatomical tract, i.e., gastrointestinal or pulmonary, accessed by the endoscope.

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)

Sandra Buchup for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051585