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Section 8. Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K122042

SEP 4 2012

Applicant Information:

Date Prepared: August 29, 2012

Name: Mauna Kea Technologies
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Contact Person: Michael A Daniel, Consultant

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Device Information:

Device Trade Name:	Cellvizio® 100 Series System and Cellvizio® System with Confocal Miniprobes™
Common Name:	Endoscope and Accessories
Classification Name(s):	Confocal Optical Imaging
Product Code/ Regulation:	OWN / 21 CFR 876.1500
Classification:	Class II

Predicate Device:

The Cellvizio® 100 Series System and the Cellvizio® System with Confocal Miniprobes™ including GastroFlex M™ miniprobes (subject of this submission) are identical in all engineering and design respects to the most recently cleared Cellvizio® 100 Series System and Cellvizio® System with Confocal Miniprobes (K120208). The Boston Scientific SpyGlass Direct Visualization Probe cleared via K050403 and K052194 has been cited as an additional predicate device.

Device Description:

The GastroFlex™ M series of Confocal Miniprobes are used as part of the Cellvizio® 100 Series system and the Cellvizio® system, to allow imaging of the internal microstructure of tissues in the gastrointestinal system accessed by an endoscope or endoscopic accessories.

The GastroFlex M™ Confocal Miniprobes are identical in all engineering and design respects to the previously cleared GastroFlex M™ Confocal Miniprobes (K120208). The reduction in size of these miniprobes was described and cleared in a previous submission (K120208). No change in design is being included in this submission. Revisions to the Indication for Use, pursuant to verification of compatibility with specialized endoscopes and endoscopic accessories, is being requested.

Indications for Use:

The GastroFlex M™ series of Confocal Miniprobes™ are intended to allow imaging of the internal microstructure of tissues in the upper gastrointestinal tract including biliary and pancreatic ducts, accessed by an endoscope or endoscopic accessories.

Comparison to Predicate Device:

No change is being made to the predicate device. The subject device is identical to the previously cleared device (K120208). The indication for use is now consistent with both the previously cleared GastroFlex M™ miniprobes (K120208) and the Boston Scientific SpyGlass Direct Visualization Probe cleared via K050403 and K052194.

Verification and validation testing has shown that the GastroFlex M™ Confocal Miniprobes are compatible with endoscopes or endoscopic accessories designed and commonly used for biliary and pancreatic imaging.

Summary:

The GastroFlex M™ Confocal Miniprobes, when used as part of the Cellvizio 100 Series and the Cellvizio Systems, have been shown to be substantially equivalent to cleared predicate devices and can be used as intended to image the internal microstructure of tissues in the gastrointestinal system. These previously cleared probes have been verified to be compatible with endoscopes and endoscopic accessories designed to be used to access the biliary tree and pancreatic ducts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 4 2012

Mauna Kea Technologies
% Daniel and Daniel Consulting
Mr. Michael A. Daniel
Regulatory Consultant
8 Snowberry Court
Orinda, California 94563

Re: K122042
Trade/Device Name: Cellvizio® 100 Series System and Cellvizio® System with Confocal Miniprobes™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OWN
Dated: August 20, 2012
Received: August 22, 2012

Dear Mr. Daniel:

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

Section 7. Indications for Use Statement

510(k) Number (if known): K122042

Device Name: Cellvizio® 100 Series System and Cellvizio® System with Confocal Miniprobes™

Indications for Use:

The GastroFlex M™ series of Confocal Miniprobes™ are intended to allow imaging of the internal microstructure of tissues in the upper gastrointestinal tract including biliary and pancreatic ducts, accessed by an endoscope or endoscopic accessories.

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)

Neil R Ogden for MKM

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

510(k) Number K122042