APR 1 8 2013

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: K123676

Applicant Information:

Date Prepared: November 21, 2012

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

Phone Number: (415) 407-0223
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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 AQ-Flex 19 Confocal Miniprobes are identical in all respects to the Confocal Miniprobe GastroFlex M most recently cleared with Cellvizio 100 Series System and Cellvizio System with Confocal Miniprobes, K120208.
- Endoscopic UltraSound Needles : Expect Endoscopic Aspiration Needle (K112198 from Boston Scientific), EchoTip Ultra Ultrasound Needle System (K083330 from Cook Endoscopy) and EchoTip Ultra High Definition Ultrasound Access Needle (K092359 from Cook Ireland Ltd)

Device Description:

The subject device, "AQ-Flex 19" is a member of the GastroFlex M family of devices cleared via K122042 and K120208. It is identical in design to the GastroFlex M devices described in K120208. There are no differences in design, materials, or function between the subject AQ-Flex 19 device and the recently cleared GastroFlex M devices.

A locking accessory is being added to the package as an aid to secure placement inside a EUS-FNA needle in place of a Stylet. Instructions for Sterilization have also been added.

Indications for Use:

The Cellvizio 100 Series System with Confocal Miniprobes is a confocal laser system with fiber optic probes that is intended to allow imaging of the internal microstructure of tissues in anatomical tracts, i.e., gastrointestinal.

The AQ-Flex 19TM member of the GastroFlex M series of Confocal Miniprobes can be used within anatomical tracts, i.e., gastrointestinal, accessed by an endoscope or endoscopic accessories, including through EUS-FNA needles.

Comparison to Predicate Device:

No change is being made to the subject/predicate device. The subject device is identical to the previously cleared device (K120208). The indication for use is being expanded to include selected needle-based endoscopic procedures.

Verification and validation testing has shown that the AQ-Flex 19 Confocal Miniprobes are compatible with endoscopes or endoscopic accessories designed and commonly used in these procedures (such as endoscopic needles).

Summary:

The AQ-Flex 19 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 a variety of anatomical locations. These previously cleared probes have been verified to be compatible with endoscopes and endoscopic accessories designed to be used in these applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 18, 2013

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

Re: K123676
Trade/Device Name: Cellvizio 100 Series and Cellvizio Systems with Confocal Miniprobes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OWN
Dated: April 01, 2013
Received: April 02, 2013

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, FOR

Peter D. Rümm -S

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

Enclosure

Section 7.Indications for Use Statement

510(k) Number (if known): _____K123676_____

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

Indications for Use:
The Cellvizio 100 Series System with Confocal Miniprobes is a confocal laser system with fiber optic probes that is intended to allow imaging of the internal microstructure of tissues in anatomical tracts, i.e., gastrointestinal.

The AQ-Flex 19TM member of the GastroFlex M series of Confocal Miniprobes can be used within anatomical tracts, i.e., gastrointestinal, accessed by an endoscope or endoscopic accessories, including through EUS-FNA needles.

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 -S
2013.04.17 15:47:52 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K123676