Section 7: Premarket Notification 510(k) Summary

A. Submitter Information

i. Company name and address

Mauna Kea Technologies
9 rue d'Enghien
75010 Paris
France

Mauna Kea Technologies

ii. Contact name

Chris Tihansky (Official Correspondent)
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iii. Date prepared

July 22th, 2011

B. Name of the device

i. Proprietary name

Cellvizio® 100 Series (Cellvizio® 100 Series System with Confocal Miniprobes™)

ii. Model number

Cellvizio® 100 Series System with F400-v2
Confocal Miniprobes™:

- ColoFlex™ (Z and UHD types),
- GastroFlex™ (Z and UHD types), and
- AlveoFlex™

iii. Common names

Cellvizio®, Cellvizio® 100 Series, Confocal Miniprobes™, ColoFlex™, GastroFlex™, and AlveoFlex™

iv. Classification name

Endoscope and/or Accessories (21 CFR 876.1500)

v. Classification

Class II

vi. Product Code

GCJ

C. Predicate device(s) information

Device Name	Manufacturer	Premarket Notification 510(k) No.	Clearance Date
Cellvizio® F-400 System	Mauna Kea Technologies	K051585	September 6, 2005
Cellvizio® (-GI, -LUNG) with Confocal Miniprobe™ (Coloflex, Gastroflex, Alveoflex)	Mauna Kea Technologies	K061666	August 24, 2006

D. Device description

Cellvizio® 100 Series is a confocal laser imaging system with a variety of fiber optic probes (Confocal Miniprobes™) that is intended to allow confocal laser imaging of the internal microstructure of tissues in anatomical tracts, i.e. gastrointestinal or respiratory, accessed through an endoscope.
Cellvizio® 100 Series is based on a common laser scanning technology adapted for imaging through a bundle of optical fibers which is the raw component of the Confocal Miniprobes™.

Cellvizio® 100 Series is composed of several components, including:

- Main opto-electronical components:
  - Laser Scanning Unit (LSU)
  - Confocal Miniprobes™
  - Confocal Processor with Cellvizio® Software
- Peripherals:
  - Foot-switch
  - Keyboard
  - Trackball
  - Screen
  - Video converter
  - Isolation transformer
- User documentation: Cellvizio® 100 Series System User Guide, Confocal Miniprobes™ User Guide and Reprocessing Instructions
- Accessories (such as Cletop-S Confocal Miniprobes™ connector cleaning system, Confocal Miniprobes™ clip, storage box, caps, spare fuses)

All components are integrated into a cart.

E. Intended use

Cellvizio® 100 Series is intended to allow confocal laser imaging of the internal microstructure of tissues in anatomical tracts, i.e. gastrointestinal or respiratory, accessed through an endoscope.

The intended use of the device has not changed since the K051585 and K061666 clearances.

F. 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 or respiratory, accessed by an endoscope or endoscopic accessories.

G. Comparison to predicate device(s) & Performance data

The comparison to the predicate devices was based on a review of the Company's 510(k) Premarket Notifications K051585 and K061666, that refer to previously cleared versions of the Cellvizio® device.
This submission is being made for device modifications that do not alter the scientific premise, technological characteristics or intended use of the device.

The changes made to the device that are reflected in this Special 510(k) have been made and evaluated in accordance with the Company's Quality Management System and Design Control process, which is certified as ISO 9001 and ISO 13485 compliant, and it has been determined that the upgrades made to the system do not introduce any new concerns related to the safety or effectiveness compared to the predicate devices and the data presented herein demonstrate that the device continues to operate as intended.

Bench testing has been conducted to confirm that the device satisfies the performance requirements for its intended use. Results of bench testing show that the upgrades made to the system do not introduce any new concerns related to the safety or effectiveness compared to the predicate devices. Additionally, comparison of images obtained in bench testing, using representative tissue samples with both the upgraded system and the predicate devices demonstrates that both software and hardware updates do not affect image quality and imaging performance.

H. Conclusions

The testing demonstrates that Cellvizio® 100 Series is equivalent to predicate devices and can be used as intended to allow imaging of the internal microstructure of tissues in anatomical tracts, i.e., gastrointestinal or respiratory, accessed by an endoscope or endoscopic accessories.

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

Mauna Kea Technologies, Inc.
% TUV Rheinland of North America, Inc.
Mr. Michael S. Ogunleye
12 Commerce Road
Newton, Connecticut 06470

AUG - 8 2011

Re: K111047
Trade/Device Name: Cellvizio® 100 Series System with Confocal Miniprobes™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OWN
Dated: July 22, 2011
Received: July 27, 2011

Dear Mr. Ogunleye:

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 6: Indications for Use Statement

510(k) Number:
K111047

Device Name:

Cellvizio® 100 Series 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 or respiratory, accessed by an endoscope or endoscopic accessories.

Prescription Use AND/OR	Over-The-Counter Use
_____X_____	_____
(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.P. Ogden for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111047