Section 7. Premarket Notification "510(k) Summary"

JUL 2 5 2014

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

510(k) Number: K133466

Applicant Information [807.92(a)(1)]:

Date Prepared:	July 23, 2014
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Device Information [807.92(a)(2)]:

Device Trade Name:	Cellvizio® 100 Series System with Confocal Miniprobes™
Device Model:	Cellvizio® 100 Series F700-v2 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(s) [807.92(a)(3)]:

- Cellvizio® 100 Series System with Confocal Miniprobes™ (K111047)
- Cellvizio® (-GI, -Lung) with Confocal Miniprobe™ (K061666)

Device Description: [807.92(a)(4)]:

The subject device, "Cellvizio® 100 Series F700-v2 system with Confocal Miniprobes" operates in the same way as the predicate devices in order to provide confocal images of the internal microstructure of tissues in anatomical tracts. The only difference between the devices is the laser used for imaging at 785nm, along with the filters that have been adapted to this wavelength. The Cellvizio® 100 Series F700-v2 system is equipped with a laser emitting at 785nm whereas predicate devices are equipped witha laser emitting at 488nm or 660nm.

This alternative laser, working at 785nm, allows confocal imaging of tissues with similar quality as the 488nm laser previously-cleared with the Cellvizio® 100 Series system in K111047.

510(k) Summary Continued:

Intended Use / Indications for Use [807.92(a)(5)]:

The Cellvizio® 100 Series F700-v2 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.

Summary of the Technological Characteristics compared to the Predicate Device [807.92(a)(6)]:

The updated Cellvizio® 100 Series F700-v2 system, using a laser emitting at 785nm, has the following similarities to the Cellvizio® 100 Series F400-v2 system which previously received 510(k) concurrence:

- same Indications for use;
- same operating principle;
- incorporates the same basic design;
- incorporates the same materials and is packaged using the same materials and processes.

The only difference between the subject and the predicate devices is the laser used for confocal imaging, along with the filters adapted to its wavelength. The other elements of the Confocal Imaging system are unchanged.

Mauna Kea Technologies Confocal Miniprobes™, designed and commonly used in imaging the internal microstructure of tissues in anatomical tracts, have been verified to be compatible with the Cellvizio® 100 Series F700-v2 system, and to provide similar image performance as the predicate device.

Performance Data on which Substantial Equivalence is Based [807.92(b)(1) and (2)]:

1) Laser safety testing in conformance with IEC 60825-1 2007 Laser Safety
2) 21 CFR Part 1040 Performance standards for light emitting products
3) Spectral Sensitivity evaluation
4) Electrical Safety testing in conformance with applicable portions of IEC 60601-1-1:2000 and IEC 60601-1-2:2001 and IEC 60601-1-4 and IEC 60601-2-18
5) Software validation

Conclusions Drawn from Performance Data [807.92(b)(3)]

Conclusions from the performance data collected (listed above) are:

1) The laser conforms with requirements of IEC 60825-1:2007;
2) Requirements of 21 CFR Part 1040 are met;
3) Spectral sensitivity meets all requirements;
4) The product conforms to all electrical safety requirements, and
5) Product software has been satisfactorily validated.

In summary, the Cellvizio® 100 Series F700-v2 system with Confocal Miniprobes™ described in this submission is substantially equivalent to the predicate devices.

Additional Information [807.92(d)]

None.

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

July 25, 2014

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

Re: K133466
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: June 25, 2014
Received: June 26, 2014

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 contact the Division of Industry and Consumer Education 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133466

Device Name
Cellvizio 100 Series System with Confocal Miniprobes

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.07.25 09:05:14 -04'00'

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