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

September 25, 2014

Mauna Kea Technologies
% Mr. Michael A. Daniel
Daniel and Daniel Consulting
340 Jones Lane
Gardnerville, Nevada 89460

Re: K141358
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: August 27, 2014
Received: August 29, 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)*
K141358

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 are intended to allow imaging of the internal microstructure of tissues.

The CystoFlex UHD R Confocal Miniprobe can be used within anatomical tracts, i.e., urinary, including, but not limited to, urethra, bladder, and ureter, accessed through 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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 7. 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: K141358

Applicant Information:

Date Prepared: May 6, 2014

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

Phone Number: (415) 407-0223
Office: (775) 392-2970
Facsimile Number: (775) 392-2972

Device Information:

Device Trade Name: Cellvizio® 100 Series 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:

- Regarding the Cellvizio Confocal Imaging System, the **Cellvizio 100 Series System** has been cleared in K111047.
- Regarding the compatibility of the access during urological procedures in rigid cystoscopes and the visualization and examination of the urinary tract, the CystoFlex UHD R Confocal Miniprobe is substantially equivalent to the previously cleared **UroFlex B Confocal Miniprobe** (K132389).

Device Description:

The CystoFlex UHD R Confocal Miniprobe, when used as part of the Cellvizio 100 Series system and the Cellvizio system, is intended to allow confocal laser imaging of the internal microstructure of tissues in anatomical tracts, i.e., urinary, including, but not limited to, urethra and bladder, accessed through an endoscope or endoscopic accessories.

The CystoFlex UHD R Confocal Miniprobe is similar in design to the UroFlex B Confocal Miniprobe, except for its distal optical head, which is a UHD-type distal head. The CystoFlex UHD R Confocal Miniprobe can be inserted into endoscope lumens with inner diameter equal to or higher than 2.8mm, allowing them to work in currently used rigid cystoscopes.

Indications for Use:

The Cellvizio® 100 Series System with Confocal Miniprobes™ is a confocal laser system with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues.

The CystoFlex™ UHD R Confocal Miniprobe can be used within anatomical tracts, i.e., urinary, including, but not limited to, urethra, bladder, and ureter, accessed through an endoscope or endoscopic accessories.

Comparison to Predicate Device:

No change is being made to the fundamental technology and operating principle of the previously cleared UroFlex™ B Confocal Miniprobe used in this submission as a predicate device (K132389). The CystoFlex UHD R is identical to this predicate device, only differing by the design of its distal optical head ("UHD-type" for the CystoFlex™ UHD R instead of "Z-type" for the UroFlex™ B). The indications for use is unchanged and remains to image the urinary tract during endoscopic procedures.

Due to this UHD-type distal optical head, the CystoFlex™ UHD R is designed to fit into rigid cystoscopes with working channel ≥ 2.8 mm.

Verification and validation testing provides proof that the modifications meet the design specifications and user needs, and biocompatibility testing provides evidence that there are no changes to the biocompatibility of the device.

Summary:

Based upon the intended use, indications for use, product technical information, performance testing and biocompatibility information provided in this premarket notification, the CystoFlex™ UHD R Confocal Miniprobe, when used as part of the Cellvizio 100 Series and the Cellvizio Systems, has been shown to be substantially equivalent to the UroFlex™ B Confocal Miniprobe, and can be used as intended to image the internal microstructure

of tissues in the urinary tract during endoscopic procedures. This Confocal Miniprobe has been verified to be compatible with cystoscopes that are designed to be used in these applications.