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

May 20, 2016

Mauna Kea Technologies
c/o Michael A. Daniel
Daniel & Daniel Consulting
340 Jones Lane
Gardenville, NV, 89460

Re: K160416
Trade/Device Name: Cellvizio® 100 Series Systems with Confocal Miniprobes™
CelioFlex™ UHD 5-C Confocal Miniprobe
CystoFlex™ UHD R-C Confocal Miniprobe
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: April 18, 2016
Received: April 21, 2016

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,

Jennifer R. Stevenson -A

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

6. Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 *See PRA Statement below.*
Indications for Use	

510(K) Number (if known)

K160416

Device Name

CystoFlex UHD R-C and CelioFlex UHD 5-C used with Cellvizio 100 Series (800)

◦ Indications for Use *(Describe)*

Cellvizio® 100 Series Systems with Confocal Miniprobes™ are confocal laser systems with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues.

CelioFlex™ UHD 5-C Confocal Miniprobe is intended to be used by qualified physicians to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures.

CystoFlex™ UHD R-C 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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FORM FDA 3881 (1/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

1. 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: 160416

Applicant Information:

Date Prepared: February 12, 2016

Name:	Mauna Kea Technologies
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Contact Person:	Michael A Daniel, Consultant madaniel@clinregconsult.com
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Facsimile Number:	(610) 545-0799

Device Information:

Device Trade Name:	CelioFlex™ UHD 5-C and CystoFlex UHD R-C Confocal Miniprobes to be used with Cellvizio® 100 Series (800)
Common Name:	Endoscope and Accessories
Classification Name(s):	Confocal Optical Imaging
Product Code/ Regulation:	OWN / GCJ 21 CFR 876.1500
Classification:	Class II

Predicate Devices:

- CystoFlex UHD R has been cleared via K141358
- CelioFlex UHD 5 has been cleared via K151593

Reference Devices:

- Cellvizio 100 Series F700-V2 system with Confocal Miniprobes has been cleared via K133466.

The name of this device model has been changed for commercial reason into Cellvizio 100 Series (800) with F800-V2 and Confocal Miniprobes. The product is unchanged. The reference to 800 instead of 700 has been made to better clarify the wavelength of emission of this system, which is 785nm. This reference device will be referred by Cellvizio 100 series (800) with F800-V2 in this current submission.

Device Description:
Cellvizio® 100 Series systems with Confocal Miniprobes™ are confocal laser systems with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues.

Confocal Miniprobes are intended to be used by qualified physicians to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures.

Both CystoFlex UHD R-C and CelioFlex™ UHD 5-C have an achromatic UHD optical distal head that provide high resolution imaging for 488 to 785nm laser emission.

A "-C" suffix has been added to the commercial name of these Confocal Miniprobes compared to the predicate devices when used with a Cellvizio 100 Series (800) which has been previously cleared as Cellvizio 100 Series with F700-v2 system (K133466).

Indications for Use:

Cellvizio® 100 Series Systems with Confocal Miniprobes™ are confocal laser systems with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues.

CelioFlex™ UHD 5-C Confocal Miniprobe is intended to be used by qualified physicians to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures.

CystoFlex™ UHD R-C 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 Previous Devices:

No change is being made to the fundamental technology and operating principle of the previously cleared CystoFlex™ UHD R & CelioFlex™ UHD 5 Confocal Miniprobes (K141358 & K151593). Commercial name of these Confocal Miniprobes has been changed when they are used with a Cellvizio 100 Series (800).

Intended use and indications for use of the CystoFlex™ UHD R-C and CelioFlex™ UHD 5 are the same as the predicate devices (K141358 & K151593).

Testing Completed:

All the verification and validation testing were performed on predicate devices (CystoFlex™ UHD R and CelioFlex™ UHD 5 confocal Miniprobes) and reference device and have shown that subject devices (CystoFlex™ UHD R-C and CelioFlex™ UHD 5-C) meet the design specification and user needs. The following tests were performed:

- Biocompatibility (Cytotoxicity, Sensitization, Irritation or Intracutaneous reactivity & Systemic toxicity) according to:

  - ISO 10993-1:2009 “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”,
  - ISO 10993-5:2009 “Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity”,
  - ISO 10993-10:2010 "Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity",
  - ISO 10993-11:2009 “Biological evaluation of medical devices - Part 11: Tests for systemic toxicity”

- Resistance to reprocessing methods: mechanical resistance, tensile strength assessment, functional testing, image quality etc. according to
  - Our internal specifications regarding the number of uses for each Confocal Miniprobes model and
  - AAMI TIR 12:2010 "Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers"

- Efficacy of reprocessing methods has been tested according to

  - AAMI TIR 12:2010 "Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers" and
  - AAMI TIR 30:2011 “A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices”

- Laser safety has been tested compliant with
  - IEC 60825-1:2007 and
  - 21 CFR 1040.10 and
  - 21 CFR 1040.11 with Laser Notice N°50.

- Imaging quality tested in compliance with the following standards:

  - ISO 8600-1:2005 “Optics and photonics -- Medical endoscopes and endotherapy devices -- Part 1: General requirements”,
  - ISO 8600-3:1997 “Optics and optical instruments – Medical endoscopes and endocopic accessories – Part 3: Determination of field of view and direction of view of endoscopes with optics” and ISO 8600-3, Amendement 1, 2003,
  - ISO 8600-4:1997 “Optics and optical instruments – Medical endoscopes and endocopic accessories – Part 4: Determination of maximum width of insertion portion”.

  - The resolution is measured according to our internal standards using 1951 USAF resolution test chart as a resolution test pattern conforming to MIL-STD-150A standard.

- Compatibility of the CystoFlex™ UHD R Confocal Miniprobe with rigid cystoscopes commonly used to image the urinary tract during endoscopic procedures has been tested and validated according to specifications for the Confocal Miniprobe, and in compliance with IEC 60601-1-6:2010 and IEC 62366:2007.

- Compatibility of the CelioFlex UHD 5 R Confocal Miniprobe with Trocar commonly used during laparoscopic procedures, tested according to specifications for the Confocal Miniprobe, and in compliance with IEC 60601-1-6:2010 and IEC 62366:2007

CystoFlex™ UHD R-C and CelioFlex™ UHD 5-C when used with Cellvizio 100 Series (800) have been tested compliant to IEC 60601-1:2005 and all applicable collateral standards.

The result from these performance evaluations demonstrated that the CystoFlex™ UHD R-C and CelioFlex™ UHD 5-C met the acceptance criteria defined in the product specification and performed comparably to the predicate device.

Summary:

Based upon the intended use, indications for use, product technical information, performance, reprocessing parameters, and biocompatibility provided in the submissions of the previously cleared devices CystoFlex™ UHD R and CelioFlex™ UHD 5, the subject devices CystoFlex™ UHD R-C and CelioFlex™ UHD 5-C Confocal Miniprobes, when used as part of the Cellvizio® 100 Series (800), have been shown to be substantially equivalent to CystoFlex™ UHD R and CelioFlex™ UHD 5 predicate devices. The subject devices are identical in technological characteristics to the Confocal Miniprobe predicate devices when used with the reference device Cellvizio 100 Series (800). Verification and validation testing provided in previous cleared 510(k) submissions demonstrate that the subject devices can safely and effectively be used to visualize and image the internal microstructure of tissues during endoscopic and laparoscopic surgical procedures.