Mauna Kea Technologies
℅ Michael Daniel
President
Daniel & Daniel Consulting
340 Jones Lane
Gardnerville, Nevada 89460

February 28, 2020

Re: K193416
Trade/Device Name: Cellvizio® I.V.E. system with Confocal Miniprobes™
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: December 7, 2019
Received: December 9, 2019

Dear Michael 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R.P. Ogden
Assistant Director, THT4A4
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193416

Device Name
Cellvizio® I.V.E. system with Confocal Miniprobes™

Indications for Use *(Describe)*
The Cellvizio® I.V.E. with Confocal Miniprobes™ is a confocal laser system with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues including, but not limited to, the identification of cells and vessels and their organization or architecture.

The GastroFlex™ N and ColoFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts. i.e., gastrointestinal systems, accessed by an endoscope or endoscopic accessories.

The AlveoFlex™ N Confocal Miniprobe™ is intended to allow imaging of anatomical tracts, i.e., respiratory systems, accessed by an endoscope or endoscopic accessories.

The CholangioFlex™ N Confocal Miniprobe™ is intended to allow imaging of the upper gastrointestinal tract including biliary and pancreatic ducts, accessed by an endoscope or endoscopic accessories.

The AQ-Flex™ 19 N Confocal Miniprobe™ is intended to allow imaging of anatomical tracts, i.e.; gastrointestinal and respiratory tracts, accessed by an endoscope, or endoscopic accessories (e.g. aspiration needles used during procedures including EUS-FNA, EBUS-TBNA and TBNA).

The CystoFlex™ F N, CystoFlex™ R N and Uroflex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., urinary, including, but not limited to, urethra, bladder, and ureter, accessed through an endoscope or endoscopic accessories.

The CelioFlex™ 5 N Confocal Miniprobe™ is intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.

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.

510(k) Summary

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

510(k) Number: K193416

Applicant Information:
Date Prepared: February 26, 2020

Name:	Mauna Kea Technologies
Manufacturer Contact Person:	Aline Criton
Address:	9 rue d'Enghien
	F-75010 Paris, France
Phone:	+33 1 48 24 03 45
Fax:	+33 1 48 24 12 18
Contact Person:	Michael A Daniel, Consultant
e-mail:	madaniel@clinregconsult.com
Phone Number:	(415) 407-0223
Facsimile Number:	(610) 545-0799

Device Information:

Device Trade Name:	Cellvizio® I.V.E. system with Confocal Miniprobes™
Common Name:	Endoscope and Accessories
Classification Name(s):	Confocal Optical Imaging
Product Code/ Regulation:	OWN / GCJ 21 CFR 876.1500
Classification:	Class II

Primary Predicate Device:
Cellvizio 100 Series System with Confocal Miniprobes (K172844).

Reference Predicate Device:
Cellvizio 100 Series Confocal Laser Imaging systems and their Confocal Miniprobes (K183640)

Device Description:
The subject device Cellvizio® I.V.E. system with Confocal Miniprobes™ is a confocal laser imaging system that can be used with a variety of Confocal Miniprobe™ (fiber optic probes) to allow real-time imaging of the internal microstructure of tissues by direct contact with the tip of the Confocal Miniprobe™ during existing medical procedures, such as endoscopy or endoscopic or open surgical procedures. The technology provides the physician with additional information in the form of real-time images during these open or minimally invasive procedures.

The Cellvizio® I.V.E. system with Confocal Miniprobes™ represents a refinement of the currently cleared and marketed predicate device, the Cellvizio® 100 Series System with Confocal Miniprobes™ (K172844). Design modifications and refinements include:

1. Improving the integration of the system in endoscopy, interventional, or surgical operating suites by reducing the global footprint of the system.

2. Improving the user interface and ease-of-use of the system by replacing the keyboard and the trackball of the Cellvizio® 100 series with a touchscreen for review and interaction with the software and the addition of a

separate remote (external) display screen for live imaging. This configuration allows better positioning of the physician's line of site during procedures.

3. Simplifying the connection of the Miniprobes to the system. This improvement has no impact on other parts of the Confocal Miniprobe design, in particular the sheathed fiber and the distal head that are the patient-contacting parts are unchanged.

4. The addition of “autofocus,” allowing automatic positioning of the laser focal point for optimal optical injection from the Optical Scanning Unit into the fibers.

The intended use, indications for use, and mechanism of action of the subject device are unchanged as compared to the 510(k) cleared Cellvizio® 100 Series System with Confocal Miniprobes™ (K172844).

Indications for Use:
The Cellvizio® I.V.E. 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 including, but not limited to, the identification of cells and vessels and their organization or architecture.

The GastroFlex™ N and ColoFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal systems, accessed by an endoscope or endoscopic accessories.

The AlveoFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., respiratory systems, accessed by an endoscope or endoscopic accessories.

The CholangioFlex™ N Confocal Miniprobes™ are intended to allow imaging of the upper gastrointestinal tract including biliary and pancreatic ducts, accessed by an endoscope or endoscopic accessories.

The AQ-Flex™ 19 N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal and respiratory tracts, accessed by an endoscope or endoscopic accessories (e.g. aspiration needles used during procedures including EUS-FNA, EBUS-TBNA and TBNA).

The CystoFlex™ F N, CystoFlex™ R N and UroFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., urinary, including, but not limited to, urethra, bladder, and ureter, accessed through an endoscope or endoscopic accessories.

The CelioFlex™ 5 N Confocal Miniprobes™ are intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.

Comparison to Predicate Device:
The Cellvizio® I.V.E. and the Cellvizio® 100 Series systems are based on the same technology and have virtually identical Confocal Miniprobes™. The two devices are substantially equivalent as:

1. Both devices have the same Intended use and indications for use. The Cellvizio® 100 Series System with Confocal Miniprobes™ (K172844) (predicate device) and the Cellvizio® I.V.E. system with Confocal Miniprobes™ (subject device) are based on the same technology of confocal laser endomicroscopy.

2. Both devices rely on an optical scanning unit and a fiber probe to propagate light between the observation area and the system in order to provide real-time imaging. The Cellvizio® I.V.E. system with confocal Miniprobes™ is basically a miniaturized version of the predicate Cellvizio® 100 Series System with Confocal

Miniprobes™ (K172844). Both systems use Confocal Miniprobes™ with identical optical design and properties (only the connector differs). Both systems are intended to be used by the same users and on the same intended patient populations.

3. There are no significant technological characteristic differences between the subject and the predicate devices. The design of the Cellvizio® I.V.E. system is based on the design of the Cellvizio® 100 Series system and has evolved in order to reduce the system footprint and to improve the usability of the device. These design changes are not significant changes and raise no new or different questions of safety and effectiveness.

Therefore, technologically the Cellvizio® I.V.E. system with Confocal Miniprobes™ is substantially equivalent to the predicate Cellvizio® 100 series system with Confocal Miniprobes™.

Testing Completed:

The following verification and validation tests were performed on the subject device:

- 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 10993-11:2017 “Biological evaluation of medical devices - Part 11: Tests for systemic toxicity”
- Effectiveness 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 2014 and
  - 21 CFR 1040.10 and 21 CFR 1040.11 with Laser Notice No. 50 and No. 56.
- Imaging quality has been tested in compliance with the following standards:
  - ISO 8600-1:2015 “Optics and photonics -- Medical endoscopes and endotherapy devices -- Part 1: General requirements”,
  - The resolution is measured according to our internal standards using 1951 USAF resolution test chart as a resolution test pattern.
- Software Verification and Validation:
  - Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The Cellvizio® I.V.E. software is considered as a “minor” level of concern.
  - The Cellvizio® I.V.E. software was developed in accordance with the IEC 62304:2006 standard (amendment 2015).
- Electrical safety and electromagnetic compatibility (EMC):
  - Electrical safety and EMC testing were conducted on the Cellvizio® I.V.E system with Confocal Miniprobes™. The system complies with the IEC 60601-1:2005/Amendment 2012, IEC 60601-2-18:2009 and 60601-1-6:2010/A1:2013 (Ed 3.1) standards for safety and the IEC 60601-1-2:2014 standard for EMC.
- Usability

- Mauna Kea Technologies has implemented a usability engineering process compliant with the IEC 62366-1:2015 standards. Compliance to this standard relies on the design control process and on the risk management process and is validated with an external laboratory (LNE).:

The results from these performance evaluations demonstrated that the Cellvizio® I.V.E system with Confocal Miniprobes™ met the acceptance criteria defined in the product specification and the performance is equivalent to the predicate device.

Conclusions:
The subject device, the Cellvizio® I.V.E system with Confocal Miniprobes™, is substantially equivalent to the predicate device Cellvizio® 100 Series System with Confocal Miniprobes™ (K172844) in terms of technological characteristics, with minor design modifications implemented. The subject device has the same principle of operation, critical performance requirements, biocompatibility, reprocessing, intended use, indications for use, and product technical information as the cleared predicate device, the Cellvizio® 100 series system with Confocal Miniprobes™.

Based upon performance testing, reprocessing parameters, biocompatibility, electrical safety, electromagnetic compatibility, and usability testing provided in this submission, the subject device Cellvizio® I.V.E system with Confocal Miniprobes™ can be used as safely and effectively to image the internal microstructure of tissues including, and not limited to, the identification of cells and vessels and their organization or architecture as the predicate. The differences in technological characteristics do not raise any different questions of safety and effectiveness. The Cellvizio® I.V.E. system with Confocal Miniprobes™ was determined to be substantially equivalent to the Cellvizio® 100 series system with Confocal Miniprobes™.