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

February 22, 2019

Re: K183640
Trade/Device Name: Cellvizio 100 Series Confocal Laser Imaging systems and their Confocal Miniprobes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN, GCJ
Dated: December 21, 2018
Received: December 26, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.02.22 09:27:22 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183640

Device Name
Cellvizio® 100 Series with Confocal Miniprobe™ AQ-Flex™ 19

Indications for Use *(Describe)*

Cellvizio® 100 Series System with Confocal Miniprobes™ are confocal laser systems 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 AQ-Flex™ 19 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 needles).

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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: K183640

Applicant Information:

Date Prepared: December 21, 2018

Manufacturer Contact:

Aline Criton
Name: Mauna Kea Technologies
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Submission Contact:

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Facsimile Number: (610) 545-0799

Device Information:

Device Trade Name: Cellvizio® 100 Series Confocal laser imaging systems and the Confocal Miniprobe™ AQ-Flex™ 19
Common Name: Endoscope and Accessories
Classification Name(s): Confocal Optical Imaging
Product Code/ Reg.: OWN / GCJ 21 CFR 876.1500
Classification: Class II

Predicate Devices:

- Previously cleared versions of Cellvizio® 100 Series Confocal laser imaging systems and the AQ-Flex™ 19 Confocal Miniprobe™ (K123676, K150831, and K172844).

Reference Devices:

- Previously cleared versions of Cellvizio® 100 Series Confocal laser imaging systems and the AlveoFlex™ Confocal Miniprobe™ (K111047, K150831, and K172844).

Device Description:

AQ-Flex™ 19 Confocal Miniprobes™ is used with Cellvizio® 100 Series system to provide imaging of anatomical tracts, i.e., gastrointestinal and respiratory tracts, accessed by an endoscope, or endoscopic accessories. It is designed to be used during transbronchial needle aspiration (TBNA), endoscopic ultrasound transbronchial needle aspiration (EBUS-TBNA) and endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) procedures.

There are no changes in design, materials, or function between the subject AQ-Flex™ 19 device and the cleared AQ-Flex™ 19 Confocal Miniprobe™ (K123676, K150831, and K172844), except for the length of the AQ-Flex 19 which has been reduced from 4 to 3 meters (AQ-Flex™ 19 Confocal Miniprobe™ has previously been cleared with a length of 4 meters).

A locking accessory already available in the package of the predicate device is used as an aid to secure placement inside the needle used during EUS-FNA procedures and can also be used during TBNA, and EBUS-TBNA procedures.

Intended 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, including, but not limited to, the identification of cells and vessels and their organization or architecture.

Indications for Use:
The AQ-Flex™ 19 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 needles).

Comparison to Predicate Device:

The Cellvizio® 100 Series systems and the AQ-Flex™ 19 Confocal Miniprobe™ remain exactly the same devices in terms of design (except for the length of the AQ-Flex™ 19 Confocal Miniprobe™ reduced from 4 to 3 meters), performance and general intended use (allow imaging of the internal microstructure) as the previously cleared devices (K123676, K150831, and K172844). The indication for use is being expanded to include selected needle-based endoscopic procedures for TBNA and EBUS-TBNA procedures.

Verification and validation testing has shown that the AQ-Flex™ 19 Confocal Miniprobes™ are compatible with endoscopes or endoscopic accessories designed and commonly used in these procedures (such as endoscopic needles).

Testing Completed:

The table below summarizes the verification and validation testing performed on predicate device (AQ-Flex™ 19 Confocal Miniprobe™) and the reference device (AlveoFlex™ Confocal Miniprobe ™) that have been provided in previous submissions K111047, K123676, K150831, and K172844 respectively.

Test performed	Acceptance Criteria	Test Results
Biocompatibility (Cytotoxicity, Sensitization, Irritation or Intracutaneous reactivity & Systemic toxicity)	All requirements met	Pass
Resistance to reprocessing methods: mechanical resistance, tensile strength assessment, functional testing, image quality etc.	All requirements met	Pass
Efficacy of reprocessing methods	All requirements met	Pass
Laser safety	All requirements met	Pass
Imaging quality	All requirements met	Pass
Compatibility of the AQ-Flex™ 19 Confocal Miniprobe™ with endoscopic accessories used during EUS-FNA procedures.	All requirements met	Pass

The potential risks associated with the use of AQ-Flex™ 19 Confocal Miniprobes™ during EBUS-TBNA and TBNA procedures have been assessed. Additional testing with endoscopic accessories used during EBUS-TBNA and TBNA was performed to validate that the AQ-Flex 19 ™ Confocal Miniprobes™ can be used during EBUS-TBNA and TBNA procedures without change of safety, performance and increase of residual risks. The same test protocols as the ones used when previously testing the AQ-Flex™ 19 Confocal Miniprobes™ for EUS-FNA in the gastro-intestinal tract have been used to assess the risks with EBUS-TBNA and TBNA accessories.

The results from these tests, summarized in the table below, demonstrate that the use of AQ-Flex ™ 19 Confocal Miniprobes™ during EBUS-TBNA and TBNA procedures does not change performance or safety and effectiveness, and do not change the global residual risk.

Test performed	Acceptance Criteria	Result
Compatibility of the AQ-Flex™ 19 Confocal Miniprobe™ with endoscopic accessories used during (EBUS)-TBNA procedures: Mechanical tests to verify no creation of sharp edges on distal head.	Verification of smooth distal surface and absence of spikes and edges on distal tip according to ISO 8600-1 standard	**Pass (25/25)**
Compatibility of the AQ-Flex™ 19 Confocal Miniprobe™ with endoscopic accessories used during (EBUS)-TBNA procedures: Confocal Miniprobe ™ strength test by insertion/extraction and bending in (EBUS)-TBNA needles.	Verification of mechanical resistance of the probe after extraction of AQ-Flex™ 19 from needle in EUS-TBNA and TBNA retroflex position	**Pass (25/25)**
Protrusion test of the of the AQ-Flex™ 19 Confocal Miniprobe™ length when used with	Securing position of AQ-Flex™ 19 distal tip with	**Pass (5/5)**

endoscopic accessories used during (EBUS)-TBNA procedures	respect to bevel tip with locking device	

Summary:

The AQ-Flex™ 19 Confocal Miniprobe™, when used as part of the Cellvizio® 100 Series, has been shown to be substantially equivalent to the cleared predicate device and can be used as intended to image the internal microstructure of tissues in a variety of anatomical locations. The previously cleared Confocal Miniprobe™ has been verified to be compatible with endoscopes and endoscopic accessories designed to be used in these applications.

Based upon the Intended Use, Indications for Use, product technical information, performances, safety and effectiveness, and biocompatibility provided in this submission and in the submissions of the previously cleared AQ-Flex™ 19 Confocal Miniprobe™ (K123676, K150831) used during EBUS-TBNA and TBNA procedures, the subject device is substantially equivalent to the predicate device. The subject device can safely and effectively be used to visualize and image the internal microstructure of tissues during endoscopic and during EBUS-TBNA and TBNA procedures.