December 15, 2017

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

Re: K172844
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: September 18, 2017
Received: September 19, 2017

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. 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.

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172844

Device Name

Cellvizio® 100 Series systems (400 and/or 800) with Confocal Miniprobes™

Indications for Use *(Describe)*

The Cellvizio® 100 Series systems (400 and/or 800) 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 GastroFlex™ (UHD, UHD-C) and ColoFlex™ (UHD, UHD-C) Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal systems, accessed by an endoscope or endoscopic accessories.

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

The CholangioFlex™ (or GastroFlex™ M) series of 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 Confocal Miniprobe™ is intended to allow imaging of anatomical tracts, i.e., gastrointestinal tracts, accessed by an endoscope or endoscopic accessories, including through EUS-FNA needles.

The CystoFlex™ (F, UHD R, UHD R-C) and Uroflex™ B of 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™ (UHD 5, UHD 5-C) of Confocal Miniprobes™ are 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.

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:

Applicant Information:

Date Prepared:	September 18, 2017
Date Revised:	November 16, 2017
Name:	Mauna Kea Technologies
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Device Information:

Device Trade Name:	Cellvizio® 100 Series Confocal laser imaging systems and their Confocal Miniprobes™
Common Name:	Endoscope and Accessories
Classification Name(s):	Confocal Optical Imaging
Product Code/Regulation:	OWN/GCJ 21 CFR876.1500
Classification:	Class II

Predicate devices:

Previously cleared versions of Cellvizio® 100 Series Confocal laser imaging systems and their Confocal Miniprobes™ (K111047, K122042, K123676, K133466, K150831, K151593, K160416, K171345).

Device Description:

The Cellvizio® 100 Series systems with Confocal Miniprobes™ are a 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.

Materials, design and intended use of the aforementioned Cellvizio® 100 Series confocal laser imaging systems and their Confocal Miniprobes™ remain exactly the same as what were previously cleared in K111047, K122042, K123676, K133466, K150831, K151593, K160416 and K171345 respectively.

Intended Use:

The 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.

The individual Confocal Miniprobes™ have been previously cleared as summarized in the following table:

Application	Mode of Operation	
	400	800
Gastrointestinal Endoscopy,	GastroFlex™ UHD (K111047, K150831) ColoFlex™ UHD (K111047, K150831) GastroFlex™ UHD-C (K133466) ColoFlex™UHD-C (K133466)	GastroFlex™ UHD-C (K133466) ColoFlex™UHD-C (K133466)
Gastrointestinal Endoscopy, including biliary and pancreatic ducts	CholangioFlex™ (or GastroFlex™M) (K122042, K150831)	
Gastrointestinal Endoscopy, Needle Endoscopy, including biliary and pancreatic ducts	AQ-Flex™ 19 (K123676, K150831)	
Lung Endoscopy	AlveoFlex™ (K111047, K150831) AlveoFlex™-C (K133466)	AlveoFlex™-C (K133466)
Urinary Endoscopy	CystoFlex™ UHD R (K150831) CystoFlex™ F (K150831) UroFlex™ B (K150831) CystoFlex™ UHD R-C (K160416)	CystoFlex™ UHD R-C (K160416)
Laparoscopy, Manual and robot-assisted laparoscopic surgery	CelioFlex™ UHD 5 (manual laparoscopy: K151593, robot-assisted laparoscopy: K171345) CelioFlex™ UHD 5-C (manual laparoscopy: K160416, robot-assisted laparoscopy: K171345)	CelioFlex™ UHD 5-C (manual laparoscopy: K160416, robot-assisted laparoscopy: K171345)

Table 1 Table summarizing cleared Confocal Miniprobe™ with models Cellvizio® 100 Series systems with K numbers.

The fundamental system capabilities in terms of optical resolution, field of view, etc. as compared to the size of cells and vessels are independent of anatomical location and for this reason, we are requesting the additional intended use wording be associated with the laser imaging system itself separate from the individual Confocal Miniprobes™. There are relatively small differences in Confocal Miniprobe™ image resolution as described below in Section 14, however all of these Confocal Miniprobe™ capabilities are well above what is required to image cells, vessels, and their organization or architecture as described in Section 14.

Indications for Use:

The 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.

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

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

The CholangioFlex™ (or GastroFlex™ M) series of 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 Confocal Miniprobe™ is intended to allow imaging of anatomical tracts, i.e., gastrointestinal tracts, accessed by an endoscope or endoscopic accessories, including through EUS-FNA needles.

The CystoFlex™ (F, UHD-R, UHD-C) and Uroflex™ B of 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™ (UHD 5, UHD 5-C) of 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 previous Devices:

The Cellvizio® 100 Series systems and its Confocal Miniprobes™ remain exactly the same devices in terms of design, performance and general intended use (allow imaging of the internal microstructure) as the previously cleared devices.

Testing Completed:

As no change is being made to the devices, all testing required has been provided in previous submissions (K111047, K122042, K123676, K133466, K150831, K151593, K160416, K171345).

Clinical demonstration based on literature review has been carried out to support this submission, as described in section 14.

Summary:

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, including robot-assisted procedures.

There are two models of the Cellvizio® 100 Series systems cleared by the FDA, the F400 (K111047) and the F800 [K160416, formerly cleared as F700-v2 system (K133466)]. All cleared Cellvizio® 100 Series Confocal Miniprobes™ are compatible with the Cellvizio® 100 Series system (400) - F400 (K111047) but not all are compatible with the Cellvizio® 100 Series system (800) - F800 (K133466, K160416) as shown in the following table (Table 2).

Cellvizio 100 Series Confocal Miniprobe™	Clearance K number	Cellvizio® 100 Series system (400) - F400 (K111047)	Cellvizio® 100 Series system (800) - F800 (K133466, K160416)
AlveoFlex™	K111047 K150831	Compatible	Not Compatible
AlveoFlex-C™	K133466	Compatible	Compatible
ColoFlex™ UHD	K111047 K150831	Compatible	Not Compatible
ColoFlex™ UHD-C	K133466	Compatible	Compatible
GastroFlex™ UHD	K111047 K150831	Compatible	Not Compatible
GastroFlex™ UHD-C	K133466	Compatible	Compatible
CystoFlex™ F	K150831	Compatible	Not Compatible
CystoFlex™ UHD R	K150831	Compatible	Not Compatible
CystoFlex™ UHD R-C	K160416	Compatible	Compatible
CelioFlex™ UHD 5	K151593, K171345	Compatible	Not Compatible
CelioFlex™ UHD 5-C	K160416, K171345	Compatible	Compatible
CholangioFlex™ (or GastroFlex™ M)	K150831, K123676	Compatible	Not Compatible
AQ-Flex™ 19	K150831, K122042	Compatible	Not Compatible
UroFlex™ B	K150831	Compatible	Not Compatible

Table 2 Compatibility of Cleared Confocal Miniprobe™ with models Cellvizio® 100 Series systems, F400 and F800.

Please note: A "-C" suffix has been added to the commercial name of Confocal Miniprobes™ to distinguish probes compatible with both Cellvizio® 100 Series systems F400 and F800 from probes compatible only with the Cellvizio® 100 Series system F400.

The objective of this submission is to clarify the previously cleared Indications for Use consistent with the proven optical resolution capabilities of the system, corresponding anatomical sizes of cells and vessels, Real World Evidence (RWE) and independent clinical findings from well-respected clinical researchers and medical societies.