



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22, 2015

Mauna Kea Technologies
Mr. Michael A. Daniel
Daniel & Daniel Consulting
340 Jones Lane
Gardneville, Nevada 89460

Re: K150831

Trade/Device Name: AQ-Flex™ (K123676); 2) UroFlex™ B (K132389); 3) CystoFlex™ UHD R (K141358); 4) ColoFlex™ UHD (K111047); GastroFlex™ UHD (Cholangioflex™) (K111047); 6) AlveoFlex™ (K111047); and 7) GastroFlex™ M (K122042)

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: Class II

Product Code: OWN

Dated: November 20, 2015

Received: November 23, 2015

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,

Binita S. Ashar -S

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 Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 <i>See PRA Statement below.</i>
510(k) Number (if known) K150831	
Device Name 1) AQ-Flex™ (K123676); 2) UroFlex™ B (K132389); 3) CystoFlex™ UHD R (K141358); 4) ColoFlex™ UHD (K111047); 5) GastroFlex™ UHD (Cholangioflex™) (K111047); 6) AlveoFlex™ (K111047); and 7) GastroFlex™ M (K122042)	
Indications for Use (Describe) ColoFlex™ UHD (K111047); GastroFlex™ UHD (Cholangioflex™) (K111047); AlveoFlex™ (K111047): The Cellvizio 100 Series System with Confocal Miniprobes is a confocal laser system with fiber optic probes that is intended to allow imaging of the internal microstructure of tissues in anatomical tracts, i.e., gastrointestinal or respiratory, accessed by an endoscope or endoscopic accessories. GastroFlex™ M (K122042): The GastroFlex M series of Confocal Miniprobes are intended to allow imaging of the internal microstructure of tissues in the upper gastrointestinal tract including biliary and pancreatic ducts, accessed by an endoscope or endoscopic accessories. AQ-Flex™ (K123676): The Cellvizio 100 Series System with Confocal Miniprobes is a confocal laser system with fiber optic probes that is intended to allow imaging of the internal microstructure of tissues in anatomical tracts, i.e., gastrointestinal. The AQ-Flex 19 member of the GastroFlex M series of Confocal Miniprobes can be used within anatomical tracts, i.e., gastrointestinal, accessed by an endoscope or endoscopic accessories, including through EUS-FNA needles. CONTINUED ON NEXT PAGE	
Type of Use (Select one or both, as applicable) <input checked="" type="checkbox"/> Prescription Use (Part 21 CFR 801 Subpart D) <input type="checkbox"/> Over-The-Counter Use (21 CFR 801 Subpart C)	
CONTINUE ON A SEPARATE PAGE IF NEEDED.	

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)
K150831

Device Name
1) AQ-Flex™ (K123676); 2) UroFlex™ B (K132389); 3) CystoFlex™ UHD R (K141358); 4) ColoFlex™ UHD (K111047);
5) GastroFlex™ UHD (Cholangioflex™) (K111047); 6) AlveoFlex™ (K111047); and 7) GastroFlex™ M (K122042)

Indications for Use (Describe)

CONTINUED FROM PREVIOUS PAGE

UroFlex™ B (K132389):

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 Uroflex™B and CystoFlex™F Confocal Miniprobes 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.

CystoFlex™ UHD R (K141358)

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)

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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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: K150831

Applicant Information:

Date Prepared: March 28, 2015

Name: Mauna Kea Technologies
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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:

- The Cellvizio 100 Series System with Confocal Miniprobes (ColoFlex™ UHD, GatroFlex™ UHD and AlveoFlex™) have been cleared in K111047.
- The CholangioFlex™ has been cleared in K122042
- The compatibility with low temperature sterilization systems has been cleared for AQ-Flex™ 19 (K123676), UroFlex™ B (K132389) and CystoFlex™ UHD R (K141358)

Device Description:

AlveoFlex™, ColoFlex™ UHD, GastroFlex™ UHD, CholangioFlex™, AQ-Flex™, UroFlex™ B and CystoFlex™ UHD R are Confocal Miniproboscopes which are compatible with specific high level disinfection and low temperature sterilization methods as described in the reprocessing instructions.

Materials, design and intended use of the aforementioned Confocal Miniproboscopes remain exactly the same as what were previously cleared in K111047, K122042, K123676, K132389 and K141358 respectively.

Low temperature sterilization methods will be added to the reprocessing instructions. Compatibility and efficacy of these methods with Confocal Miniproboscopes have been validated. The extent of validation testing relevant to this submission is provided below

1. Validation of an additional low temperature sterilization system (STERRAD 100NX EXPRESS) on AQ-Flex™ 19 (K123673), UroFlex™ B (K132389) and CystoFlex™ UHD R (K141358).
2. Validation of compatibility with low temperature sterilization systems (STERRAD 100S, and 100NX (EXPRESS)) with CholangioFlex™ (K122042), GastroFlex™ UHD, ColoFlex™ UHD and AlveoFlex™ (K111047).

Verification and validation testing confirm that GastroFlex™ UHD, ColoFlex™ UHD, AlveoFlex™ and CholangioFlex™ Confocal Miniproboscopes™ can be reprocessed safely using STERRAD® sterilization systems 100S and 100NX (EXPRESS) according to reprocessing instructions.

Indications for Use:

ColoFlex™ UHD (K111047); GastroFlex™ UHD (K111047); AlveoFlex™ (K111047):

The Cellvizio 100 Series System with Confocal Miniproboscopes is a confocal laser system with fiber optic probes that is intended to allow imaging of the internal microstructure of tissues in anatomical tracts, i.e., gastrointestinal or respiratory, accessed by an endoscope or endoscopic accessories.

GastroFlex™ M (CholangioFlex™) (K122042):

The GastroFlex M series of Confocal Miniproboscopes are intended to allow imaging of the internal microstructure of tissues in the upper gastrointestinal tract including biliary and pancreatic ducts, accessed by an endoscope or endoscopic accessories.

AQ-Flex™ 19 (K123676):

The Cellvizio 100 Series System with Confocal Miniproboscopes is a confocal laser system with fiber optic probes that is intended to allow imaging of the internal microstructure of tissues in anatomical tracts, i.e., gastrointestinal.

The AQ-Flex 19 member of the GastroFlex M series of Confocal Miniproboscopes can be used within anatomical tracts, i.e., gastrointestinal, accessed by an endoscope or endoscopic accessories, including through EUS-FNA needles.

UroFlex™ B (K132389):

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 Uroflex™B and CystoFlex™MF Confocal Miniprobes 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.

CystoFlex™ UHD R (K141358)

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 predicate devices in term of design, materials nor intended use. Subject devices are identical to previously cleared devices (AlveoFlex™, ColoFlex™ UHD, GastroFlex™ UHD (K111047)), CholangioFlex™ (K122042), UroFlex™ B (K132389), AQ-Flex™ 19 (K123676), CystoFlex™ UHD R (K141358). Further, all Confocal Miniprobes exhibit a similar external geometry. The differences between models are in the internal optical components that allow for different performance characteristics but do not substantially change the outer geometry. Further details regarding probe differences are described in tables 3, 4 and 5 of this submission and in the previously cleared K141358, K132389, K123676, K122042 and K111047 submissions and their corresponding Request for Additional Information submissions.

The only change in this submission is the addition of low temperature sterilization systems to the reprocessing instructions of the previously cleared Confocal Miniprobes (AlveoFlex™, ColoFlex™ UHD, GastroFlex™ UHD, CholangioFlex™, UroFlex™ B, AQ-Flex™ 19, CystoFlex™ UHD R). This change does not alter the fundamental technology and purpose of the previously cleared Confocal Miniprobes™.

The extension of the previously cleared AQ-Flex™ 19, UroFlex™ B and CystoFlex™ UHD R compatibility with sterilization to CholangioFlex™, ColoFlex™ UHD, GastroFlex™ UHD and AlveoFlex™ is demonstrated based on similarities in terms of design and materials between these products.

Performance Evaluation:

The following performance testing was completed:

- Functional testing post sterilization validation included visual assessment of component condition, insertion and removal tests, tensile strength and optical performance assessment. These tests also confirmed material compatibility.
- Sterilization validation was performed on the products to confirm sterility assurance levels (SAL) of 10^{-6}

- Biocompatibility per relevant portions of ISO 10993-1
 - Cytotoxicity
 - Sensitization
 - Irritation

Summary:

Based upon the intended use, indications for use, product technical information, performance testing provided in this special 510(k) submission

- AQ-Flex™ 19, UroFlex™ B and CystoFlex™ UHD R can safely and efficiently be reprocessed using STERRAD® 50, 200, 100S, 100NX EXPRESS and 100NX Duo cycles according to reprocessing instructions. Chemical resistance as well as a sterility assurance level (SAL) of 10^{-6} has been demonstrated.
- GastroFlex™ UHD, ColoFlex™ UHD, AlveoFlex™ and CholangioFlex™ Confocal Miniproboscopes can be reprocessed using STERRAD® sterilization systems 100S, 100NX EXPRESS according to reprocessing instructions as an alternative to previously cleared high-level disinfection methods. The compatibility with these sterilization methods has been demonstrated.