



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

October 23, 2015

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

Re: K151593  
Trade/Device Name: CelioFlex™ UHD 5  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: OWN, GCJ  
Dated: September 24, 2015  
Received: September 25, 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,

**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

## 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 <i>See PRA Statement below.</i>
<b>Indications for Use</b>	

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510(K) Number (if known) K151593

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Device Name  
CelioFlex™ UHD 5

◦ Indications for Use (*Describe*)

Cellvizio® 100 Series System with Confocal Miniprobess™ is a confocal laser system with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues.

CelioFlex™ UHD 5 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.

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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)

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**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**FOR FDA USE ONLY**

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Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

## 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: June 9, 2015  
 Name: Mauna Kea Technologies  
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### Device Information:

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

### Predicate Device:

- Circon's USA Series™ Laparoscope has been cleared with K013165

### Reference Devices:

- The Cellvizio 100 Series System with Confocal Miniprobosc cleared via K111047.
- The CystoFlex™ UHD R has been cleared with K141358

### Device Description:

Cellvizio® 100 Series System with Confocal Miniprobosc™ is a confocal laser system with fiber optic probes that are intended to allow imaging of the internal microstructure of tissues.

CelioFlex™ UHD 5 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. The CelioFlex™ UHD 5 confocal Miniprobe is a CystoFlex™ UHD R Confocal Miniprobe with an additional "Grabule" component and with an optical fiber of 3 meters vs. 2 meters. The Grabule is a metallic part glued to the distal tip and the adjacent part of the sheath of the CelioFlex™ UHD 5 Confocal Miniprobe. The

Grabule has been designed as a grip for laparoscopic forceps, facilitating user control of the Miniprobe distal tip during laparoscopic procedures. Both the stainless steel 316L metal comprising the Grabule and the epoxy glue (Epotek 301) used to cement the Grabule to the Miniprobe are currently used in the CystoFlex™ UHD R Miniprobe reference device. The Grabule shields the Miniprobe tip from potential wear that repeated handling by forceps might cause.

During standard laparoscopic procedures, CelioFlex™ UHD 5 Confocal Miniprobe is inserted through a pre-installed trocar. When the CelioFlex™ UHD 5 appears on the laparoscope monitor, the surgeon grasps the distal tipped Grabule with the laparoscopic fenestrated forceps to position the Confocal Miniprobe facing the tissue to be imaged.

### **Indications for Use:**

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.

CelioFlex™ UHD 5 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.

### **Comparison to Previous Devices:**

No change is being made to the fundamental technology and operating principle of the previously cleared CystoFlex™ UHD R Confocal Miniprobe (K141358). The CelioFlex™ UHD 5 is identical to this reference device, only differing by the addition of the Grabule on its distal tip and by the fiber length (2m for CystoFlex™ UHD R and 3m for CelioFlex™ UHD 5).

The Indications for Use and Intended Use of CelioFlex™ UHD R are the same as Circon's USA Series™ Laparoscopes (K013165) predicate and CystoFlex™ UHD R (K141358) reference devices, respectively.

Due to the addition of the Grabule on its distal tip, the CelioFlex™ UHD 5 is designed to fit into trocars of 4.95mm or greater.

Attached verification and validation testing demonstrates that the modifications meet the design specifications and user needs. Sterilization and biocompatibility testing provides evidence that there are no changes to the biocompatibility of the device and no changes to the efficacy and compatibility of the subject device with sterilization processes.

### **Testing Completed:**

Sterilization Efficacy Verification:	All requirements met, Test Passed
Reprocessing Sterilization Validation:	All requirements met, Test Passed
Biocompatibility (Cytotox) Validation:	All requirements met, Test Passed

**Summary:**

Based upon the Intended Use, Indications for Use, product technical information, performance, sterilization testing, and biocompatibility validation provided in this premarket notification, the CelioFlex™ UHD 5 Confocal Miniprobe, when used as part of the Cellvizio 100 Series, has been shown to be substantially equivalent to the Circon's USA Series™ Laparoscopes, and is basically identical in technological characteristics to the CystoFlex™ UHD R Confocal Miniprobe reference device. The subject device can safely and effectively be used to visualize and image the internal microstructure of tissues during endoscopic and laparoscopic surgical procedures.