May 22, 2018

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

Re: K180270
Trade/Device Name: Cellvizio 100 Series Systems with Confocal Miniprobes™
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG, OWN
Dated: January 30, 2018
Received: January 31, 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. 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,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180270

Device Name
Cellvizio® 100 Series systems with Confocal Miniprobes™

Indications for Use *(Describe)*
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 CranioFlex™ (-,-C) Confocal Miniprobes™ are indicated to provide visualization within central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection.

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: K180270

Applicant Information:

Date Prepared:	January 30, 2018
Date Revised:	May 14, 2018
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Device Information:

Device Trade Name:	CranioFlex™ (-,-C) type Confocal Miniprobes™ used with Cellvizio® 100 Series Systems
Common Name:	Neurological Endoscope
Primary Regulation and Product Code:	21 CFR 882.1480 – GWG
Secondary Product Code:	OWN
Classification Name(s):	Neurological Endoscope
Classification:	Class II

Predicate Device:

- KARL STORZ Flexible Video-Neuro-Endoscope System (K161112).

Reference devices:

- The Cellvizio® 100 Series System with Confocal Miniprobes™ cleared via K172844
- The GastroFlex™ UHD has been cleared with K111047 and K150831
- The GastroFlex™ UHD-C has been cleared with K133466

Device Description:

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. 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 and during neurosurgical procedures.

CranioFlex™ (-,-C) Confocal Miniprobes™ are used with Cellvizio® 100 Series systems to provide imaging of the brain through contact of their distal tip with the tissue. They are designed to be used and manually handled during neurosurgical procedures.

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 CranioFlex™ (-,-C) Confocal Miniprobes™ are indicated to provide visualization within central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection.

Comparison to Predicate and Reference Devices:

The CranioFlex™ (-,-C) Confocal Miniprobes™ are identical in terms of design and materials to the previously cleared GastroFlex™ (UHD, UHD-C) Confocal Miniprobes™ (K111047, K150831, K133466). It is in fact the same device. The only change being made is to the Indications.

The Indications for Use and Intended Use of CranioFlex™ (-,-C) are substantially equivalent to the KARL STORZ's Flexible Video-Neuro-Endoscope System (K161112) predicate and GastroFlex™ (UHD, UHD-C) (K111047, K150831, K133466, K172844) reference devices, respectively.

The CranioFlex™ (-,-C) are designed to be handled manually. Please reference comparison tables below:

General Comparison Table

Characteristics	Subject device	Reference devices	Predicate device	Comparison to predicate and reference devices
Device Name	Cellvizio® 100 Series System with Confocal Miniprobes	Cellvizio® 100 Series System with Confocal Miniprobes	Neuro-endoscope	Same as reference device
Manufacturer	Mauna Kea Technologies	Mauna Kea Technologies	Karl Storz GmbH & Co. KG	Same as reference device
Model	CranioFlex™, CranioFlex™-C	GastroFlex™ UHD, GastroFlex™ UHD-C,	Flexible Video-Neuro-Endoscope System	N/A
510(k)	K180270	K111047, K150831, K133466 and K172844	K161112	N/A
Regulation Number	21 CFR 876.1500 21 CFR 882.1480	21 CFR 876.1500	21 CFR 882.1480	Same as predicate device and reference device
Class	II	II	II	Unchanged
Classification Advisory Committee	General & Plastic Surgery and Neurological Devices Panel	General & Plastic Surgery	Neurological Devices Panel	Same as predicate device and reference device

Characteristics	Subject device	Reference devices	Predicate device	Comparison to predicate and reference devices
Device Class/Name	Confocal Optical Imaging	Confocal Optical Imaging	Endoscope, Neurological	Same as reference device
Product Code	GWG/OWN	OWN	GWG	Same as reference device and predicate device
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 CranioFlex™ (-,-C) Confocal Miniprobes™ are indicated to provide visualization within central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection.	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 KARL STORZ Flexible Video-Neuro-Endoscope System is indicated to provide visualization and access during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection, hydrocephalus treatment, endoscopic third ventriculostomy with choroid plexus cauterization (ETV/CPC), endoscopic third ventriculostomy, cyst fenestration, and aqueduct exploration.	Same intended use as GastroFlex™ (UHD, UHD-C) and equivalent Indications for Use to Karl Storz's Flexible Video-Neuro-Endoscope System

Technological Comparison Table

	Subject Devices CranioFlex™(-,-C)	Predicate Device Flexible Video-Neuro-Endoscope System	Comparison to predicate device
510(k) #	TBD	K161112	N/A
Operating mechanism for imaging	The tissue is illuminated by the laser light transmitted by the fibers of the Confocal Miniprobe™ through its distal objective lens. The optical signal from the tissue is collected back by the same objective and fibers. The fibers are connected to the Laser Scanning Unit (LSU) that integrates the illumination source and the optical detector. Once digitized, the signal is transmitted to the Confocal Processor™ that processes the image to be displayed on a monitor. See section 12 of submission.	LED is integrated in the handpiece of the KARL STORZ Flexible Neuro-endoscope, and it is used to provide illumination of the anatomy under examination. The light is transmitted from the LED to the distal tip via two glass fiber light bundles. The raw data captured at the distal tip CMOS (complementary metal oxide semiconductor) imaging sensor is converted to a standard NTSC (National Television System Committee) video signal by the printed circuit board (PCB), also housed in the handpiece. It allows the image to be displayed on a monitor.	Equivalent because: • Fibers to provide illumination in each case (Confocal Miniprobe™ / fiber light bundle) • A source of light and a mean to see what is illuminated in each case (LSU / LED + CMOS) A video source processor in each case (Confocal Processor™ / PCB)
Device Design / Optical components	Rigid section including objective lens, flexible optical fibers to transmit visible light to and from the tissue. See section 12 of submission	Rigid section including objective lens, flexible optical fibers to transmit visible light to and from the tissue.	Same as predicate device

	Subject Devices CranioFlex™(-,-C)	Predicate Device Flexible Video-Neuro-Endoscope System	Comparison to predicate device
Working Shaft Length	3 m	350 mm	The difference in length does not raise different questions of safety and effectiveness.
Distal Tip Diameter	2.6 mm	3.2 mm x 2.4 mm (elliptical shaped distal tip)	Equivalent
Distal Tip Cross-Sectional Surface	5.31 mm^2	6.03 mm^2	Equivalent
Outer Shaft Diameter	1.4 mm	2.9 mm	Equivalent
Working Channel Diameter	No working channel/lumen	1.2 mm	Not having a working channel does not raise different questions of safety or effectiveness.
Angle of view	0 degree, enface imaging of the surface in contact with the Confocal Miniprobe™	Deflection: • Up: 270 degrees • Down: 270 degrees	In the handpiece of the KARL STORZ Flexible Neuro-endoscope, the user has a deflection lever, which allows the distal tip to deflect 270 degrees in the up/down direction. Manipulation of the CranioFlex™ (-,-C) is manual (the physician has to handle the device with one hand). The minimal radius of curvature of the CranioFlex™ (-,-C) is 35 mm. The way the device is handled does not introduce new or different questions of safety or effectiveness.
Field of view	Microscopic imaging by contact of the distal tip of the Confocal Miniprobe™ on a diameter 240 µm	Standard neuro-endoscope have a field of view of several tens of degrees to provide enlarged visualization at a macroscopic level	The optical characteristics of the subject device are different from those of the predicate device and of any neuro-endoscope. This is due to the fact that the subject devices provide microscopic imaging with high resolution and a reduced field of view, whereas a neuro-endoscope provides a macroscopic view of a larger surgical area with a lower resolution. These differences do not raise different questions of safety and effectiveness.
Depth of observation	55 – 65 µm from the tissue surface in contact with the tip of the Confocal Miniprobe™	0 µm	
Lateral resolution	1 µm	from 250 µm down to 50 µm	
Distal Tip	Atraumatic Tip	Atraumatic Tip	Same as predicate device
Biocompatibility	Standard, Proven Inert Materials	Standard, Proven Inert Materials	Same as predicate device

Sterilization and biocompatibility testing have been previously provided for the cleared reference devices in K150831. The GastroFlex™ (UHD, UHD-C) Confocal Miniprobes™ have been tested and validated to be high level disinfected or sterilized, whereas the use of the CranioFlex™ (-, -C) Confocal Miniprobes™ during neurosurgery will require this device to be sterilized similarly to the KARL STORZ's Flexible Video-Neuro-Endoscope System (K161112) predicate.

The differences in technological characteristics between the subject devices and the predicate device do not raise different questions of safety or effectiveness. Further, there

are no different technological characteristics between the reference devices and the subject devices as described in the K111047, K150831 and K133466.

The potential risks associated with the use of CranioFlex™ (-,-C) Confocal Miniprobes™ during neurosurgical procedures have been assessed. All risks reviewed during the risk analysis of the subject devices were confirmed to be acceptable. Moreover, they do not change safety, performances nor increase residual risks, compared to the risk level of the reference devices as also reported in clinical feasibility study published in a peer reviewed journal. The global risk is therefore unchanged and remains acceptable and does not change performance, safety and effectiveness.

Summary:

Based upon the Intended Use, Indications for Use, product technical information, risk analysis, and additional biocompatibility validation provided in this premarket notification, the CranioFlex™ (-,-C) Confocal Miniprobes™, when used as part of the Cellvizio® 100 Series, have been shown to be substantially equivalent to the KARL STORZ's Flexible Video-Neuro-Endoscope System, and are identical in technological characteristics to the GastroFlex™ (UHD, UHD-C) Confocal Miniprobes™ reference devices. The differences in technological characteristics' between the subject devices and the predicate device do not raise different questions of safety or effectiveness. Thus, the subject devices can safely and effectively be used to provide visualization within the central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection.