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

January 24, 2020

Re: K191144
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, GCJ, GWG
Dated: December 19, 2019
Received: December 20, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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.P. Ogden
Assistant Director, THT4A4
DHT4A: Division of General Surgery Devices
OHT5: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K191144

Device Name
Cellvizio® 100 Series system with Confocal Miniprobes™

Indications for Use *(Describe)*
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 including, but not limited to, the identification of cells, vessels and their organization or architecture. The Cellvizio® 100 Series System F400-v2 is indicated for imaging blood flow in vascular areas, including microvasculature and capillaries.

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

The AlveoFlex™ Confocal Miniprobe™ is intended to allow imaging of anatomical tracts, i.e., respiratory systems, accessed by an endoscope or endoscopic accessories.

The CholangioFlex™ series of Confocal Miniprobe™ is 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 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).

The CystoFlex™ (F, UHD-R) 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 of Confocal Miniprobe™ is intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.

The CranioFlex™ Confocal Miniprobe™ is 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.

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2 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: K191144

Applicant Information:

Date Prepared: January 24, 2020

Manufacturer Contact Person: Aline Criton
Name: Mauna Kea Technologies
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F-75010 Paris, France
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Facsimile Number: (610) 545-0799

Device Information:

Device Trade Name:	Cellvizio® 100 Series Confocal laser imaging systems with Confocal Miniprobes™
Common Name:	Endoscope and Accessories Neurological Endoscope
Classification Name(s):	Confocal Optical Imaging
Primary regulation and Product Code:	OWN / GCJ 21 CFR 876.1500
Secondary regulation and Product Code:	GWG 21 CFR 882.1480
Classification:	Class II

Predicate Devices:

- Previously cleared versions of Cellvizio® 100 Series Confocal laser imaging system with Confocal Miniprobe™ (K172844, K180270 and K183640).

Reference Devices:

- The Zeiss CONVIVO (K181116).

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 including, but not limited to, the identification of cells, vessels and their organization or architecture. The Cellvizio® 100 Series System F400-v2 is indicated for imaging blood flow in vascular areas, including microvasculature and capillaries.

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

The AlveoFlex™ Confocal Miniprobe™ is intended to allow imaging of anatomical tracts, i.e., respiratory systems, accessed by an endoscope or endoscopic accessories.

The CholangioFlex™ series of Confocal Miniprobe™ is 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 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).

The CystoFlex™ (F, UHD-R) and UroFlex™ B of Confocal Miniprobe™ 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 of Confocal Miniprobe™ is intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.

The CranioFlex™ Confocal Miniprobe™ is indicated to provide visualization within central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection.

Device Description:
Confocal Miniprobes™ are used with Cellvizio® 100 Series System (F400-v2), which is a confocal imaging system with fiber optic probes which allows visualization of internal microstructure of tissues and blood flow including, but not limited to, the identification of cells, vessels and their organization or architecture, during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures and during neurosurgical procedures.

Fluorescein Sodium is used as a fluorescence contrast agent to allow imaging of microvasculature and visualization of blood flow. Fluorescein Sodium can be used as a contrast agent with Cellvizio® 100 Series system with Confocal Miniprobes™ without change of formulation, mode of action, approved dose or route of administration; it is delivered independent of Cellvizio® 100 Series system in accordance with Fluorescein Sodium instruction for use.

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 K172844, K180270 and K183640.

Comparison to Predicate Device:
The table below details the difference in Indications for Use between the subject device and the previously cleared predicate device (See Table 7-1).

Aspect	Subject Device Cellvizio® 100 Series System F400-V2 with Confocal Miniprobes™ with Fluorescein	Predicate Device Cellvizio® 100 Series System F400-V2 with Confocal Miniprobes™	Comparison to predicate
Device Name	Cellvizio® 100 Series System with Confocal Miniprobes™	Cellvizio® 100 Series System with Confocal Miniprobes™	Unchanged
Manufacturer	Mauna Kea Technologies 9 Rue d'Enghien F-75010 Paris, France	Mauna Kea Technologies 9 Rue d'Enghien F-75010 Paris, France	Unchanged
Model	Cellvizio® 100 Series F400-V2 with Confocal Miniprobes™	Cellvizio® 100 Series F400-V2 with Confocal Miniprobes™	Unchanged
510 (k)#	Not Assigned	K172844, K180270, and K183640	/
Regulation Number	21 CFR 876.1500 21 CFR 882.1480	21 CFR 876.1500 21 CFR 882.1480	Unchanged
Class	II	II	Unchanged
Classification Advisory Committee	General & Plastic Surgery and Neurological Devices Panel	General & Plastic Surgery and Neurological Devices Panel	Unchanged
Device Class / Name	Confocal Optical Imaging	Confocal Optical Imaging	Unchanged
Product Code	OWN/GCJ/GWG	OWN/GCJ/GWG	Unchanged
Combination Device	Yes	No	Extension of the Indications for Use with Fluorescein Sodium dye

Indication For Use	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 including, but not limited to, the identification of cells, vessels and their organization or architecture. The Cellvizio® 100 series system F400-V2 is indicated for imaging blood flow in vascular areas, including microvasculature and capillaries. The CranioFlex™ Confocal Miniprobe™ is indicated to provide visualization within central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection. The GastroFlex™ UHD and ColoFlex™ UHD Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal systems, accessed by an endoscope or endoscopic accessories. The AlveoFlex™ Confocal Miniprobe™ is 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™ is 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 and respiratory tracts accessed by an endoscope or endoscopic accessories, including through endoscopic needles. The CystoFlex™ (F, UHD R) and UroFlex™ B 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 Confocal Miniprobe™ is intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.	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, including, but not limited to, the identification of cells and vessels and their organization or architecture. The CranioFlex™ Confocal Miniprobe™ is indicated to provide visualization within central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection. The GastroFlex™ UHD and ColoFlex™ UHD Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal systems, accessed by an endoscope or endoscopic accessories. The AlveoFlex™ Confocal Miniprobe™ is 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™ is 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 and respiratory tracts accessed by an endoscope or endoscopic accessories, including through endoscopic needles. The CystoFlex™ (F, UHD R) and UroFlex™ B Confocal Miniprobe™ 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 Confocal Miniprobe™ is intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.	There is an extension of the Indication For Use of the Cellvizio® 100 series system F400-V2 to visualize blood flow with Fluorescein Sodium contrast agent. The indications for use of the different Confocal Miniprobes ™ do not change.

Table 7-1: Comparison of Indication for Use between the Subject Device and Previously Cleared Predicate Device

The table below further demonstrates the substantial equivalence of the subject device to the predicate device.

Aspect	Comparison of Predicate Device to Cellvizio® 100 Series system with Confocal Miniprobes™, with extended Indications for Use with Fluorescein Sodium contrast agent
Technical equivalence	No change of design and performances Same technical design Same operating principle Same safety profile and risk level Identical technological characteristics Same reprocessing methods Same device packaging
Biological equivalence	Same biocompatible patient-contacting materials and same biocompatibility tests requirements Same target tissues to image
Application and usage equivalence	Same intended use of the device Same environment of use and same intended user Same instructions for use and operating procedure Same precautions and safety instructions

Table 7-2: Comparison of Predicate Device to Cellvizio® 100 Series system with Confocal Miniprobes™, with new Indications for Use.

Comparison to Reference Device:

The table below provides the comparison between the subject device and the reference device (Zeiss CONVIVO Confocal Endomicroscopy system K181116).

Attribute	Subject Device Cellvizio® 100 Series System F400-V2 with Confocal Miniprobes™ with Fluorescein	Reference Device CONVIVO K181116	Comparison to Reference
Device name	Cellvizio® 100 Series System with Confocal Miniprobes™	CONVIVO	/
Manufacturer	Mauna Kea Technologies 9 Rue d'Enghien F-75010 Paris, France	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 D-07745 Jena, Germany	/
510(k)	Not Assigned	K181116	/
Classification Product Code	GWG (primary product code) OWN (secondary product code)	GWG (primary product code) OWN (secondary product code)	Same
Regulation No.	21 CFR 882.1480 21 CFR 876.1500	21 CFR 882.1480 21 CFR 876.1500	Same
Class	II	II	Same
Classification Adv. Committee	General & Plastic Surgery and Neurological Devices Panel	General & Plastic Surgery and Neurological Devices Panel	Same
Device Class / Name	Confocal Optical Imaging	Confocal Optical Imaging	Same
Product Code	OWN/GCJ/GWG	OWN/GCJ/GWG	Same
Combination Device	Yes	Yes	Both devices can be used with Fluorescein Sodium as a contrast agent to image blood flow.
Indications for use	The Cellvizio® 100 Series system with Confocal Miniprobes™ is a confocal laser system with fiber optic probes that is	The ZEISS CONVIVO is a surgical endomicroscope intended for viewing intra-operative blood flow in the cerebral	Similar Indication for Use for blood

	intended to allow imaging of the internal microstructure of tissues including, but not limited to, the identification of cells, vessels and their organization or architecture. Cellvizio® 100 series F400-V2 is indicated for imaging blood flow in vascular areas, including microvasculature and capillaries. The CranioFlex™ Confocal Miniprobe™ is indicated to provide visualization within central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection. The GastroFlex™ UHD and ColoFlex™ UHD Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal systems, accessed by an endoscope or endoscopic accessories. The AlveoFlex™ Confocal Miniprobe™ is 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™ is 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 and respiratory tracts accessed by an endoscope or endoscopic accessories, including through endoscopic needles. The CystoFlex™ (F, UHD R) and UroFlex™ B 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 Confocal Miniprobe™ is intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures	vascular area, including microvasculature and capillaries. The CONVIVO's fiber optic scanner probe is placed in direct contact with tissue during cranial diagnostic and therapeutic procedures, such as tumor biopsy and resection, to create in-vivo confocal laser scanning images of the internal microstructure of tissues.	flow visualization with Fluorescein Sodium
Device Description	Standalone confocal endomicroscope for intraoperative imaging with high magnification.	Standalone confocal endomicroscope for intraoperative imaging with high magnification.	Same
Basic System Function	Create in-vivo confocal laser scanning images of the internal microstructure of tissue.	Create in-vivo confocal laser scanning images of the internal microstructure of tissue.	Same
Imaging System	Confocal laser scanning system with fiber optic probe	Confocal laser scanning system with fiber optic probe	Same
Optical Visualization	Fiber scanner Photo detector	Fiber scanner Photo detector	Same
Display	Monitor	Monitor	Same

Fluorescent Agent	Tissue autofluorescence and Fluorescence imaging system used with Fluorescein Sodium yields fluorescent image with very high magnification of the distribution of the fluorescein sodium dye in the imaged tissue during the operation.	Fluorescence imaging system used with Fluorescein Sodium yields fluorescent image with very high magnification of the distribution of the fluorescein Sodium dye in the imaged tissue during the operation.	Same
Visualization of Real-Time images	9 to 12Hz	1 to 3 Hz	Similar/ Real time imaging
Fluorescence Excitation	488 nm	488 nm	Same
Physical Method of Illumination	Laser source (continuous blue light of 488 nm wavelength); Fluorescence	Laser source (continuous blue light of 488 nm wavelength); Fluorescence	Same
Physical Method of Imaging	Confocal Laser Scanning system	Confocal Laser Scanning system	Same
Actions ensured by the software	Control of the laser-scanning unit and of the laser emission, reconstruction of images process, display of images on a screen.	Control of the laser-scanning unit and of the laser emission, reconstruction of images process, display of images on a screen.	Same
Export	Via DICOM PACS, Shared Drive and USB thumb drives.	Via DICOM PACS, Shared Drive and USB thumb drives	Same
Laser	Class 2M laser product	Class 3R laser product	Similar with lower laser power for the subject device

Table 7-3: Comparison of Indication for Use between the Subject Device and Previously Cleared Reference Device

The Cellvizio® 100 series system F400-V2 with the CranioFlex™ Confocal Miniprobe and the reference device, CONVIVO (K181116), have the same indication for use. They are both used to examine blood flow in the cerebral vascular area. In both cases, Fluorescein Sodium is injected into the patient, excitation light is shined onto the tissue and emitted fluorescent light is used to observe the blood flow and the vasculature within the brain. While the systems have differences, they each have the functions for viewing and recording fluorescent images. Both devices use Fluorescein Sodium as a contrast agent to visualize vascular structures without changes to the formulation, mode of action, approved dose or route of administration. Fluorescein Sodium is used in an identical manner for both devices.

The resolution and optical characteristics of the Confocal Miniprobes™ are identical or similar to the resolution and optical characteristics of the CranioFlex™ Confocal Miniprobes™. Therefore, blood flow can be image with all Confocal Miniprobes™.

The Cellvizio® 100 series system with F400-V2 with all Confocal Miniprobes™ device, also enables visualization of blood flow with Fluorescein Sodium for a different Indication for Use (imaging of gastrointestinal, respiratory ad urinary tracts, body cavities, organs and canals accessed by an endoscope, or endoscopic accessories, during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures) but a generally equivalent intended use (tissue microstructures imaging).

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, K172844, K180270 and K183640).

Clinical demonstration based on literature review has been carried out to support this submission, as described in section 13.

Summary:

The Cellvizio® 100 Series system F400-v2 with its Confocal Miniprobes™ used with Fluorescein Sodium contrast agent remains exactly the same device in terms of design, performance and general intended use (allow imaging of the internal microstructure) as the previously cleared devices.

The subject device (the Cellvizio® 100 Series system (F400-v2) (with Confocal Miniprobes™) used with Fluorescein Sodium Contrast Agent) has the same indications for use as the predicate device (the Cellvizio® 100 Series system (F400-v2) (with Confocal Miniprobes™)) since both devices are intended to be used to image the tissue microstructures.

The objective of this submission is to extend the previously cleared Indications for Use with the visualization of blood flow when using Fluorescein Sodium as a contrast agent with the proven optical resolution and real time imaging 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 international independent Health Technology Assessment organizations.

The subject device and the reference CONVIVO device are intended to visualize both internal microvascularization and microstructure of tissues. The devices are tools that are used to provide imaging information to the physician.

Both devices are intended to be brought into direct contact with the tissue to be examined to create in-vivo confocal laser scanning images of the internal microstructure of tissue.

Furthermore, both devices are confocal laser systems with fiber optic probes and have the identical operation principle. Both devices use a laser source which emits a continuous blue light of 488 nm wavelength. With both devices, a monitor is used to view the images –the images generated with the scanner probe are displayed on the monitor. Both devices can be used in real-time during procedures.

The subject device, Cellvizio® 100 Series system (F400-v2) with Confocal Miniprobes™ used with Fluorescein Sodium, and the reference device, CONVIVO used with Fluorescein Sodium, have the same Indication for Use. They are both used to examine blood flow in vascular areas.