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

August 18, 2021

Re: K212322
Trade/Device Name: Cellvizio I.V.E. system with Confocal Miniprobes
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: OWN, GCJ
Dated: July 23, 2021
Received: July 26, 2021

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 and Part 809); 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, M.S.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212322

Device Name
Cellvizio® I.V.E. system with Confocal Miniprobes™

Indications for Use *(Describe)*
The Cellvizio® I.V.E. 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 Cellvizio® I.V.E. system is indicated for imaging blood flow in vascular areas, including microvasculature and capillaries.

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

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

The CholangioFlex™ N 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 N Confocal Miniprobes™ are 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 but not limited to EUS-FNA, EBUS-TBNA and TBNA).

The CystoFlex™ F N, CystoFlex™ R N and UroFlex™ N 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™ 5 N 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.

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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: K212322

Applicant Information:
Date Prepared: August 6, 2021

Manufacturer Contact Person: Aline Criton
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Device Information:

Device Trade Name:	Cellvizio® I.V.E. system with Confocal Miniprobes™
Common Name:	Confocal Optical Imaging
Classification Name(s):	Endoscope and Accessories
Primary regulation and Product Code:	OWN 21 CFR 876.1500
Secondary regulation and Product Code:	GCJ 21 CFR 876.1500
Classification:	Class II

Predicate Device:

The Cellvizio® 100 Series system with Confocal Miniprobes™ cleared as a drug-device combination with Fluorescein Sodium via 510(k) K191144 serves as the predicate device.

Reference Device:

The Cellvizio® I.V.E. system with Confocal Miniprobes™ is the reference device via 510(k) K193416.

Indications for Use:
Cellvizio® I.V.E. 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® I.V.E. system is indicated for imaging blood flow in vascular areas, including microvasculature and capillaries.

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

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

The CholangioFlex™ N 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 N Confocal Miniprobes™ are 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 but not limited to EUS-FNA, EBUS-TBNA and TBNA).

The CystoFlex™ F N, CystoFlex™ R N and UroFlex™ N 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™ 5 N Confocal Miniprobes™ are intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.

Device Description:
Confocal Miniprobes™ are used with Cellvizio® I.V.E. system, 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.

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

Materials, design and intended use of the aforementioned Cellvizio® I.V.E. system Confocal laser imaging systems and its Confocal Miniprobes™ remain exactly the same as what were previously cleared in K193416 and were found to be substantially equivalent to the Cellvizio® 100 series system Confocal laser imaging system and its Confocal Miniprobes™ (cleared via K172844) without Fluorescein Sodium. A reference to the use of Sodium Fluorescein was added to the Cellvizio 100 Series System with Confocal Miniprobes (K172844) via K191144 on 01/24/2020. The sole purpose of this submission is to extend the previously cleared Indications for Use of Cellvizio® I.V.E. system Confocal laser imaging systems and its Confocal Miniprobes™ with the visualization of blood flow in vascular areas, including microvasculature and capillaries when using Sodium Fluorescein as a contrast agent.

Comparison to Predicate Device:
The table below details the differences between the subject device and the previously cleared predicate device (See Table 1-1).

Attribute	Subject Device Cellvizio® I.V.E. System with Confocal Miniprobes™ with Fluorescein	Predicate Device Cellvizio® 100 Series System with Confocal Miniprobes™ with Fluorescein	Comparison to Predicate
Device name	Cellvizio® I.V.E. System with Confocal Miniprobes™	Cellvizio® 100 Series System with Confocal Miniprobes™	/
Model	I.V.E.	100 series F400-v2	/
Confocal MiniProbe™ Names	ColoFlex™ N, GastroFlex™ N, CystoFlex™ R N, CelioFlex™ 5 N, AlveoFlex™ N, AQ-Flex™ 19 N, CystoFlex™ F N, UroFlex™ N, CholangioFlex™ N	ColoFlex™ UHD, GastroFlex™ UHD, CystoFlex™ UHD R, CelioFlex™ UHD 5, AlveoFlex™ , AQ-Flex™ 19, CystoFlex™ F, UroFlex™ B, CholangioFlex™	/
Manufacturer	Mauna Kea Technologies 9 Rue d'Enghien F-75010 Paris, France	Mauna Kea Technologies 9 Rue d'Enghien F-75010 Paris, France	Same
510(k)	K212322	K191144	/
Classification Product Code	OWN (primary product code) GCJ (secondary product code)	OWN (primary product code) GWG (secondary product code)	Same
Regulation No.	21 CFR 876.1500	21 CFR 882.1480 21 CFR 876.1500	Same
Class	II	II	Same
Classification Adv. Committee	General & Plastic Surgery l	General & Plastic Surgery	Same
Device Class / Name	Confocal Optical Imaging	Confocal Optical Imaging	Same
Product Code	OWN/GCJ	OWN/GCJ	Same
Combination Device	Yes	Yes	Both systems have co-packaging with Sodium Fluorescein
Indications for use	The Cellvizio® I.V.E. 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 Cellvizio® I.V.E. system is indicated for imaging blood flow in vascular areas, including microvasculature and capillaries. The GastroFlex™ N and ColoFlex™ N Confocal Miniprobes™ are intended to allow imaging of	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, including, but not limited to, the identification of cells and 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	Identical Indications for Use including blood flow visualization in vascular areas, including microvasculature and capillaries with Fluorescein Sodium

	anatomical tracts, i.e., gastrointestinal systems, accessed by an endoscope or endoscopic accessories. The AlveoFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., respiratory systems, accessed by an endoscope or endoscopic accessories. The CholangioFlex™ N 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 N Confocal Miniprobes™ are 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 but not limited to EUS-FNA, EBUS-TBNA and TBNA). The CystoFlex™ F N, CystoFlex™ R N and UroFlex™ N 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™ 5 N Confocal Miniprobes™ are intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.	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.	
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.	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.	Same
Fluorescence Excitation	488 nm	488 nm	Same
Physical Method of Illumination	Laser source (continuous blue light of 488 nm wavelength); Fluorescence. Maximum output power: 15 mW	Laser source (continuous blue light of 488 nm wavelength); Fluorescence Maximum output power: 15 mW	Same
Physical Method of Imaging	Confocal Laser Scanning system.	Confocal Laser Scanning system	Same
Laser classification	Class 2M laser product	Class 2M laser product	Same
Scanning system	Proximal (in the OSU) Same mirrors types and manufacturer with a lower footprint for the scanning boards	Proximal (in the LSU) 4 kHz horizontal scanning with resonant mirror vertical scanning with galvanometric mirror	Same technology (cleared via K193416)
Illumination output	Class 2M visible laser light at 488 nm when a N model Confocal Miniprobe is connected	Class 2M visible laser light at 488 nm when a Confocal Miniprobe is connected	Same
Detection Bandwidth	500-650 nm	500 - 650 nm	Same
Location of Single Point Optical Signal Detector	In the eBox that receives the optical signal from the OSU electronic BOX connected to the scanner body through an optical fiber	In the Laser Scanning Unit connected to the Confocal Miniprobe™	Found substantially equivalent (cleared via K193416)
Location of signal analog to digital conversion	On eBox motherboard	On specific CSU board in LSU	Found substantially equivalent (cleared via K193416)
Location of signal processing	On eBox motherboard	On computer motherboard after digital signal is transferred from LSU through Firewire cable	Found substantially equivalent (cleared via K193416)
Firmware algorithm	Same functions with equivalent algorithm except for the autofocus	Mirror scanning control, Digitization of the laser signal, Interlock laser (laser safety mechanisms de-activating the laser power), EEPROM read/write	Found substantially equivalent (cleared via K193416)

Image processing algorithm	Same algorithm with addition of automatic adjustment of laser focus in the fiber bundle	Proprietary algorithm including fiber bundle calibration, and image reconstruction	Found substantially equivalent (cleared via K193416)
Output video format	SDI, DVI and other numerical video format / conversion performed in eBox	SDI, DVI and other numerical format, through video converters	Found substantially equivalent (cleared via K193416)
Dimensions of imaging system	Footprint < 70cmx70cm (wheels) / <35cm*40cm (body) Weight: <40 kg	Footprint < 80cmx80cm (wheels and body) Weight: 131 kg	Found substantially equivalent (cleared via K193416)
Field of view	Circular, 240 µm, 325 µm or 600 µm diameter depending on the Confocal Miniprobe model	Circular, 240 µm, 325 µm or 600 µm diameter depending on the Confocal Miniprobe model	Same
Depth of observation	Fixed, 0 µm, 40-70 µm or 55-65 µm with axial resolution 5 or 15 µm depending on the Confocal Miniprobe model	Fixed, 0 µm, 40-70 µm or 55-65 µm with axial resolution 5 or 15 µm depending on the Confocal Miniprobe model	Same
Lateral resolution	1 µm or 3.5 µm depending on the model of Confocal Miniprobe	1 µm or 3.5 µm depending on the model of Confocal Miniprobe	Same
Visualization of Real-Time images	9 to 12Hz	9 to 12Hz	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, time stamping and review of images acquired.	Control of the laser-scanning unit and of the laser emission, reconstruction of images process, display of images on a screen, time stamping and review of images acquired.	Same
Export	Via DICOM PACS, Shared Drive and USB thumb drives.	Via DICOM PACS, Shared Drive and USB thumb drives.	Same

Table 1-1: Comparison of the subject device with previously cleared predicate device

As described in K193416, the cleared Cellvizio® I.V.E. system and its Confocal Miniprobes™ represent a refinement to Cellvizio® 100 series system and its Confocal Miniprobes™ (K172844). Design modifications and refinements included:

1. Improving the integration of the system in endoscopy, interventional, or surgical operating suites by reducing the global footprint of the system.
2. Improving the user interface and ease-of-use of the system by replacing the keyboard and the trackball of the Cellvizio® 100 series with a touchscreen for review and interaction with the software and the addition of a separate remote (external) display screen for live imaging. This configuration allows better positioning of the physician's line of site during procedures.
3. Simplifying the connection of the Miniprobes to the system. This improvement has no impact on other parts of the Confocal Miniprobe design, in particular the sheathed fiber and the distal head that are the patient-contacting parts are unchanged.
4. The addition of "autofocus," allowing automatic positioning of the laser focal point for optimal optical injection from the Optical Scanning Unit into the fibers.

The subject device, the Cellvizio® I.V.E. system (with Confocal Miniprobes™) used with Fluorescein Sodium Contrast Agent) has the same intended use and indication for uses than the predicate device (the Cellvizio® 100 Series system (with Confocal Miniprobes™) since both devices are intended to be used to image the tissue microstructures and blood flow in vascular areas, including microvasculature and capillaries when used in combination with Fluorescein Sodium dye. The subject device is similar in terms of design to the cleared predicate device as it:

- has the same operating principle, the same technological characteristics, and the same design;
- is constructed with the same biocompatible materials and meets the same biocompatibility tests requirements;
- is reprocessed with the same methods;

- has the same device packaging with a co-packaging with Sodium Fluorescein.

The subject and predicate devices, when used in combination with Sodium Fluorescein dye, have the same intended use and indications for use. The differences between subject device, the Cellvizio® I.V.E. system with Confocal Miniprobes™ and the predicate device (K191144), including revisions to the User Interface, System footprint and Connector can have no effect upon the system's ability to be used with Sodium Fluorescein and the imaging of blood flow indication. The Cellvizio® I.V.E. system, in the exact same manner as K191144, can be used to examine blood flow in vascular areas, including microvasculature and capillaries.

Comparison to Reference Device:
The table below details the Indications for Use between the subject device and the previously cleared reference device (See Table 1-2).

Attribute	Subject Device Cellvizio® I.V.E. System with Confocal Miniprobes™ with Fluorescein	Reference Device Cellvizio® I.V.E. System with Confocal Miniprobes™	Comparison to Reference
Device name	Cellvizio® I.V.E. System with Confocal Miniprobes™	Cellvizio® I.V.E. System with Confocal Miniprobes™	Same
Model	I.V.E.	I.V.E.	Same
Confocal MiniProbe™ Names	ColoFlex™ N, GastroFlex™ N, CystoFlex™ R N, CelioFlex™ 5 N, AlveoFlex™ N, AQ-Flex™ 19 N, CystoFlex™ F N, UroFlex™ N, CholangioFlex™ N	ColoFlex™ N, GastroFlex™ N, CystoFlex™ R N, CelioFlex™ 5 N, AlveoFlex™ N, AQ-Flex™ 19 N, CystoFlex™ F N, UroFlex™ N, CholangioFlex™ N	Same
Manufacturer	Mauna Kea Technologies 9 Rue d'Enghien F-75010 Paris, France	Mauna Kea Technologies 9 Rue d'Enghien F-75010 Paris, France	Same
510(k)	K212322	K193416	/
Classification Product Code	OWN (primary product code) GCJ (secondary product code)	OWN (primary product code) GCJ (secondary product code)	Same
Regulation No.	21 CFR 876.1500	21 CFR 876.1500	Same
Class	II	II	Same
Classification Adv. Committee	General & Plastic Surgery l	General & Plastic Surgery l	Same
Device Class / Name	Confocal Optical Imaging	Confocal Optical Imaging	Same
Product Code	OWN/GCJ	OWN/GCJ	Same
Combination Device	Yes	No	Subject device now includes co-packaging with Sodium Fluorescein
Indications for use	The Cellvizio® I.V.E. 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 Cellvizio® I.V.E. system is indicated for imaging blood flow in vascular areas, including microvasculature and capillaries. The GastroFlex™ N and ColoFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal systems, accessed by an endoscope or endoscopic accessories.	The Cellvizio® I.V.E. 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 GastroFlex™ N and ColoFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., gastrointestinal systems, accessed by an endoscope or endoscopic accessories. The AlveoFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., respiratory systems, accessed by an endoscope or endoscopic accessories.	Indications for Use of the subject device has been extended for blood flow visualization when used with Sodium Fluorescein as a contrast agent

	The AlveoFlex™ N Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., respiratory systems, accessed by an endoscope or endoscopic accessories. The CholangioFlex™ N 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 N Confocal Miniprobes™ are 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 but not limited to EUS-FNA, EBUS-TBNA and TBNA). The CystoFlex™ F N, CystoFlex™ R N and UroFlex™ N 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™ 5 N Confocal Miniprobes™ are intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.	The CholangioFlex™ N 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 N Confocal Miniprobes™ are 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 but not limited to EUS-FNA, EBUS-TBNA and TBNA). The CystoFlex™ F N, CystoFlex™ R N and UroFlex™ N 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™ 5 N Confocal Miniprobes™ are intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.	
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.	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.	Same
Fluorescence Excitation	488 nm	488 nm	Same
Physical Method of Illumination	Laser source (continuous blue light of 488 nm wavelength); Fluorescence. Maximum output power: 15 mW	Laser source (continuous blue light of 488 nm wavelength); Fluorescence. Maximum output power: 15 mW	Same
Physical Method of Imaging	Confocal Laser Scanning system.	Confocal Laser Scanning system.	Same
Laser classification	Class 2M laser product	Class 2M laser product	Same
Scanning system	Proximal (in the OSU) Same mirrors types and manufacturer with a lower footprint for the scanning boards	Proximal (in the OSU) Same mirrors types and manufacturer with a lower footprint for the scanning boards	Same
Illumination output	Class 2M visible laser light at 488 nm when a N model Confocal Miniprobe is connected	Class 2M visible laser light at 488 nm when a N model Confocal Miniprobe is connected	Same
Detection Bandwidth	500-650 nm	500-650 nm	Same
Location of Single Point Optical Signal Detector	In the eBox that receives the optical signal from the OSU electronic BOX connected to the scanner body through an optical fiber	In the eBox that receives the optical signal from the OSU electronic BOX connected to the scanner body through an optical fiber	Same
Location of signal analog to digital conversion	On eBox motherboard	On eBox motherboard	Same
Location of signal processing	On eBox motherboard	On eBox motherboard	Same
Firmware algorithm	Same functions with equivalent algorithm except for the autofocus	Same functions with equivalent algorithm except for the autofocus	Same
Image processing algorithm	Same algorithm with addition of automatic adjustment of laser focus in the fiber bundle	Same algorithm with addition of automatic adjustment of laser focus in the fiber bundle	Same
Output video format	SDI, DVI and other numerical video format / conversion performed in eBox	SDI, DVI and other numerical video format / conversion performed in eBox	Same

Dimensions of imaging system	Footprint < 70cmx70cm (wheels) / <35cm*40cm (body) Weight: <40 kg	Footprint < 70cmx70cm (wheels) / <35cm*40cm (body) Weight: <40 kg	Same
Field of view	Circular, 240 µm, 325 µm or 600 µm diameter depending on the Confocal Miniprobe model	Circular, 240 µm, 325 µm or 600 µm diameter depending on the Confocal Miniprobe model	Same
Depth of observation	Fixed, 0 µm, 40-70 µm or 55-65 µm with axial resolution 5 or 15 µm depending on the Confocal Miniprobe model	Fixed, 0 µm, 40-70 µm or 55-65 µm with axial resolution 5 or 15 µm depending on the Confocal Miniprobe model	Same
Lateral resolution	1 µm or 3.5 µm depending on the model of Confocal Miniprobe	1 µm or 3.5 µm depending on the model of Confocal Miniprobe	Same
Visualization of Real-Time images	9 to 12Hz	9 to 12Hz	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, time stamping and review of images acquired.	Control of the laser-scanning unit and of the laser emission, reconstruction of images process, display of images on a screen, time stamping and review of images acquired.	Same
Export	Via DICOM PACS, Shared Drive and USB thumb drives.	Via DICOM PACS, Shared Drive and USB thumb drives.	Same

Table 1-2: Comparison the subject device and previously cleared reference device

The Cellvizio® I.V.E. system with its Confocal Miniprobes™ used with Sodium Fluorescein contrast agent remains exactly the same device in terms of design, technology, performance and general intended use (allow imaging of the internal microstructure) as the previously cleared reference device (K193416).

The subject device is identical in terms of design to the cleared reference device as it:

- has identical operating principle, identical technological characteristics, and identical design;
- is constructed with identical biocompatible materials and meets the same biocompatibility tests requirements;
- is reprocessed with the same methods;
- has the same device packaging except for the co-packaging with Sodium Fluorescein.

The objective of this submission is to extend the previously cleared Indications for Use with the visualization of blood flow in vascular areas, including microvasculature and capillaries when using Fluorescein Sodium.

Testing Completed:

As no technical change is being made to the subject/reference device, all testing required has been provided in the previous submission (K193416).

The subject device, Cellvizio® I.V.E. system with Confocal Miniprobes™ used with Fluorescein Sodium, and the previously cleared predicate device, Cellvizio® 100 Series system with Confocal Miniprobes™ used with Fluorescein Sodium, have the same Indications for Use. They are both used to examine blood flow in the tissue vascular area.

The subject device, the Cellvizio® I.V.E. system with Confocal Miniprobes™ and the previously cleared predicate device, the Cellvizio® 100 series system with Confocal Miniprobes™, are used in the same way in combination with Sodium Fluorescein.

The subject device, the Cellvizio® I.V.E. system with Confocal Miniprobes™ and the previously cleared predicate device, the Cellvizio® 100 series system with Confocal Miniprobes™, have the same maximum laser output and therefore no additional testing was performed to ensure safety when the subject device is used in combination with Sodium Fluorescein.

Co-packaging testing

The design of the Cellvizio® I.V.E product and the Confocal Miniprobes™ model is unchanged with respect to K193416. For Cellvizio® I.V.E. to be used as a combination product, Confocal Miniprobes™ model will be delivered co-packaged with Sodium Fluorescein vials in an identical way as the one described and cleared in K191144. The components of the co-package will be assembled into the same shipper box that can fit all configurations that has been validated in K191144. Empty spaces due to differences in size of package between the different Confocal Miniprobe models will be filled by folded paper or cardboard fillers in an identical fashion to the cleared predicate device. Therefore, no additional testing was performed for the co-packaging of Sodium Fluorescein with Cellvizio® I.V.E the Confocal Miniprobes™.

Summary:

The subject/modified device Cellvizio® I.V.E. system with its Confocal Miniprobes™ used with Fluorescein Sodium contrast agent is exactly the same device in terms of design and performance as the previously cleared device (K193416).

The objective of this submission is to extend the previously cleared Indications for Use with the visualization of blood flow in vascular areas, including microvasculature and capillaries when using Fluorescein Sodium as a contrast agent.

The device is brought into direct contact with tissue to be examined to create *in-vivo* confocal laser scanning images of the internal microstructure of tissue.

The subject device is a confocal laser system with fiber optic probes and has the identical operation principle as the previously cleared co-packaged combination predicate device (K191144). Both devices use a laser source which emits a continuous blue light of 488 nm wavelength with the same maximum output power. 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® I.V.E. system with Confocal Miniprobes™ used with Sodium Fluorescein, and the previously cleared predicate device, Cellvizio® 100 Series system with Confocal Miniprobes™ used with Sodium Fluorescein, have the same Indications for Use. They are both used to examine blood flow in the tissue vascular area.