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:

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Device Information:

Device Trade Name:	CelioFlex™ UHD Confocal Miniprobes to be used with Cellvizio® 100 Series Systems
Common Name:	Endoscope and Accessories
Classification Name(s):	Confocal Optical Imaging
Product Code/Regulation:	OWN/GCJ 21 CFR876.1500
Classification:	Class II

Predicate devices:

The CelioFlex™ UHD 5 has been cleared with K151593

The CelioFlex™ UHD 5-C has been cleared with K160416

Device Description:

CelioFlex™ UHD Confocal Miniprobes™ are used with Cellvizio® 100 Series systems to provide imaging of the internal microstructure of body cavities, organs, and canals through contact of their distal tip with the tissues. They are designed for use during laparoscopic surgical procedures, including robot-assisted procedures.

CelioFlex™ UHD Confocal Miniprobes™ have a “grabule” (previously cleared in K151593 and K160416) on their distal tip. The “grabule” has been designed as a grip for laparoscopic grasping accessories, facilitating user control of the miniprobe distal tip during conventional laparoscopic procedures while preventing potential wear to the Miniprobe tip that repeated handling by forceps might cause. The diameter of the “grabule” is fitted for insertion of

CelioFlex™ UHD Confocal Miniprobes™ through trocars with diameter larger or equal to 5 mm.

CelioFlex™ UHD Confocal Miniprobes are also compatible with laparoscopy robot-assisted procedures. Robotic arm graspers can be used to manipulate CelioFlex™ UHD Confocal Miniprobes.

During robotic-asisted procedures, CelioFlex™ UHD Confocal Miniprobes™ are inserted through a pre-installed trocar. When the CelioFlex™ UHD distal end appears on the monitor, the surgeon uses the robotic accessory to grasp the distal part of the Confocal Miniprobe™ or "grabule", with the laparoscopic grasper to position the Confocal Miniprobe™ facing the tissue to be imaged.

Intended Use:

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.

Indications for Use:

CelioFlex™ UHD Confocal Miniprobes™ are intended to be used by qualified physicians to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic and laparoscopic surgical procedures, including robotic-assisted procedures.

Comparison to previous Devices:

CelioFlex™ UHD Confocal Miniprobes™ are already cleared for conventional laparoscopic procedures and have been thoroughly tested for this indication (K151593).

The subject devices are strictly identical to the predicate devices in terms of design, technological characteristics, and operating principle. The performances of the subject devices are thus unchanged in terms of imaging performances, biocompatibility, reprocessing, and laser safety, electrical safety and EMC when used with the Cellvizio® 100 Series systems. The Intended Use of the subject devices also remains the same as that of predicate devices.

Robotic accessories are more and more commonly used during laparoscopic procedures and the only difference in robot-assisted procedures is that the Confocal Miniprobe is handled by robotic grasping accessories instead of hand-held grasping accessories.

Testing Completed:

The table below summarizes the verification and validation testing performed on predicate devices (CelioFlex™ UHD 5 and CelioFlex™ UHD 5-C Confocal Miniprobes™) that have been provided in previous submissions K151593 and K160416 respectively.

Test performed	Acceptance Criteria	Test Results
Biocompatibility (Cytotoxicity, Sensitization, Irritation or Intracutaneous reactivity & Systemic toxicity)	All requirements met	Pass
Resistance to reprocessing methods: mechanical resistance, tensile strength assessment, functional testing, image quality etc.	All requirements met	Pass
Efficacy of reprocessing methods	All requirements met	Pass
Laser safety	All requirements met	Pass
Imaging quality	All requirements met	Pass
Compatibility of the CelioFlex™ UHD Confocal Miniprobes with Trocars commonly used during laparoscopic procedures.	All requirements met	Pass

The potential risks associated with the use of CelioFlex™ UHD Confocal Miniprobes™ during robot-assisted laparoscopy procedures have been assessed and additional testing with representative worst case robot grasping tools was performed to validate that the CelioFlex™ UHD Confocal Miniprobes™ can be used during robot-assisted laparoscopic procedures without change of safety, performances and increase of residual risks. The result from these tests, summarized in the table below, have demonstrated that the use of CelioFlex™ UHD Confocal Miniprobes™ during robot-assisted laparoscopic procedures does not change performance or safety and effectiveness, and does not affect image quality and does not change the global residual risk.

Test performed	Acceptance Criteria	Result
Grasp and Release Test with grasping robotic accessory (100 handling cycles with 8 samples)	The CelioFlex™ UHD Confocal Miniprobes must complete the testing without loss of imaging performance or broken and/or loose components	Pass
Bend and Flexibility Test with grasping robotic accessory (40 handling cycles with 8 samples)	The CelioFlex™ UHD Confocal Miniprobes must complete the testing without loss of imaging performance or broken and/or loose components	Pass

Summary:

Based upon the Intended Use, Indications for Use, product technical information, performances, safety and effectiveness, and biocompatibility provided in this submission and in the submissions of the previously cleared CelioFlex UHD 5 (K151593) and CelioFlex UHD 5-C (K160416), CelioFlex™ UHD Confocal Miniprobes™ used in robotic-assisted surgery procedures are substantially equivalent to predicate devices. The subject devices can safely and effectively be used to visualize and image the internal microstructure of tissues during endoscopic and laparoscopic surgical procedures, including robotic-assisted procedures.