February 13, 2026

VPIX Medical, Inc.
Kyungmin Hwang
President
774, Gyeryong-ro, Jung-gu
Daejeon, 34873
Korea, South

Re: K251852
Trade/Device Name: cCeLL - In vivo with Drop-In Robo (CN100-2W2C488775, CN100-1W1C775, DR200)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN, GCJ
Dated: May 30, 2025
Received: June 17, 2025

Dear Kyungmin Hwang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSICA CARR -S

Jessica Carr, Ph.D.
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: 07/31/2026

See PRA Statement below.

510(k) Number *(if known)*
K251852

Device Name
cCeLL - In vivo with Drop-In Robo (CN100-2W2C488775, CN100-1W1C775)

Indications for Use *(Describe)*
The cCeLL - In vivo with Drop-In Robo is a confocal laser system with fiber optic probe 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.

Upon intravenous administration and use of an ICG consistent with its approved labeling, the cCeLL - In vivo with Drop-In Robo is used to perform fluorescence angiography.

Upon administration and use of ICG consistent with its approved labeling, the cCeLL - In vivo with Drop-In Robo is used to perform fluorescence imaging to support the visual assessment of vessels, blood flow, and related tissue perfusion.

The Drop-In Robo is intended to provide visualization of 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.

In accordance with 21 CFR 807.92 the 510(k) Summary for the cCeLL – In vivo with Drop-In Robo is provided below.

i.   *Submitter Information*

Submitter:	VPIX Medical, Inc.
	774, Gyeryong-ro, Jung-gu
	Daejeon, 34873
	Republic of Korea
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Phone:	+82 (0)42 535 0668
Date Prepared:	February 13, 2026

ii.   *Device Name*

Proprietary Name:	cCeLL - In vivo with Drop-In Robo
Manufacturer:	VPIX Medical, Inc.
Common Name:	Confocal Optical Imaging
Classification Name:	Endoscope and accessories
Regulation Number:	21 CFR 876.1500
Device Class:	Class II
Product Code:	OWN (Primary)
	GCJ (Secondary)

iii.   *Predicate Devices*

<u>Primary Predicate</u>

510(k) Number	K220477
Proprietary Name:	Cellvizio 100 Series System with Confocal Miniprobes
Manufacturer:	Mauna Kea Technologies
Common Name:	Confocal Optical Imaging
Classification Name:	Endoscope and accessories
Regulation Number:	21 CFR 876.1500; 21 CFR 882.1480
Device Class:	Class II
Product Code:	OWN (Primary)
	GCJ, GWG (Secondary)

Reference Device

510(k) Number	K233391
Proprietary Name:	cCeLL – In vivo
Manufacturer:	VPIX Medical, Inc.
Common Name:	Neurological Endoscope
Classification Name:	Endoscope, Neurological
Regulation Number:	21 CFR 882.1480; 21 CFR 876.1500
Device Class:	Class II
Product Code:	GWG (Primary)
	OWN (Secondary)

iv.   *Device Description*

The cCeLL - In vivo with Drop-In Robo, 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.

To achieve this function, the cCeLL - In vivo with Drop-In Robo has been designed:

- To excite fluorescent components within the human tissue with the laser light emitted by the Main Unit at 775nm.
- To receive fluorescence signal emitted from tissue microstructures within the spectral detection bandwidth of the Main Unit 813-850 nm.

The indocyanine green absorbs light in the near-infrared region with peak absorption at 805 nm and emits fluorescence (light) at a slightly longer wavelength, with peak emission at 830 nm.

The device can excite ICG in the vascular system and image signal emitted by ICG in the vascular system after ICG has been administered to the patient according to its approved labeling dose.

v.   *Principle of Operation / Mechanism of Action*

This product irradiates the tissue with a laser by contacting the probe to the target tissue of a patient injected with a drug with fluorescence characteristics (indocyanine green, not included in the composition of this product.) It is a medical fluorescence imaging device that measures the intensity of the fluorescence signal emitted from the

tissue and images the cells of the tissue. It has a function to acquire an image of a part corresponding to an area of several hundred μm of tissue at a depth of several to several hundred μm by using fluorescence and shows a two-dimensional image through the provided software.

vi.   *Indications for Use*

The cCeLL - In vivo with Drop-In Robo is a confocal laser system with fiber optic probe 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.

Upon intravenous administration and use of an ICG consistent with its approved labeling, the cCeLL - In vivo with Drop-In Robo is used to perform fluorescence angiography.

Upon administration and use of ICG consistent with its approved labeling, the cCeLL - In vivo with Drop-In Robo is used to perform fluorescence imaging to support the visual assessment of vessels, blood flow, and related tissue perfusion.

The Drop-In Robo is intended to provide visualization of organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.

vii.   *Summary of Substantial Equivalence*

The similarities between subject device and predicate device are as follows:
Both devices provide HD images of NIR Indocyanine green (ICG) dye fluorescence during robot-assisted surgery in adults.
Both include a confocal imaging system and fiber optic probes as part of the cleared system configuration.
Both can be used with any medical grade HD monitor with a DVI-D input.

The differences between subject device and predicate device are as follows:
The predicate provides 800-905 nm detection bandwidth, but the subject device provides 813-850nm.
The predicate allows use of Pafolacianine dye fluorescence also, but subject device allows Indocyanine green (ICG) only.
The predicate provides 0-65 μm depth of observation, but subject device provides 44.6 μm depth of observation.
The predicate provides Circular, diameters of 240, 325, and 600 μm field of view, but subject device provides 500 μm × 500 μm Field of view.
The predicate provides 1-3.5 μm lateral resolution, but subject device provides 2.19 μm lateral resolution.
The predicate provides up to 40 mW Fluorescence excitation power, but subject device provides up to 3.5 mW Fluorescence excitation power.
Please refer to the table, below, for additional comparison details.

Substantial Equivalence Table:

	Subject Device K251852	Primary Predicate K220477	Reference Device K233391	Comparison
510(k) Number	K251852	K220477	K233391	N/A
Device Name	Trade Name: cCeLL - In vivo with Drop-In Robo Classification Name: Endoscope and accessories	Trade Name: Cellvizio 100 Series System with Confocal Miniprobes Classification Name: Endoscope and accessories	Trade Name: cCeLL - In vivo Classification Name: Neurological Endoscope	N/A
Product Code	OWN (Primary) GCJ	OWN GCJ GWG	GWG (Primary) OWN (Secondary)	Identical
Regulation	21 CFR 876.1500	21 CFR 876.1500 21 CFR 882.1480	21 CFR 882.1480 21 CFR 876.1500	Identical
Classification Name	Endoscope Accessories	Endoscope Accessories	Neurological Endoscope	Identical
Device Description	Drop-In Robo is used with cCeLL - In vivo 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.	Confocal Miniprobes™ are used with Cellvizio® 100 series (F800) 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.	The cCeLL - In vivo is used to provide real-time high-definition (HD) endoscopic images of nearinfrared(NIR) indocyanine green (ICG) dye fluorescence during minimally invasive, neurosurgery in adults. The overall system includes a 7 mm Pixection ICG/NIR Endoscope (0°) for use in neurosurgery, a light source for emission of NIR illumination, a photo-multiplier tube capable of capturing NIR imaging, and a sterile probe sheath. The cCeLL - In vivo can be used with any medical grade HD monitor with a DVI-D or RGB input.	Identical

	Subject Device K251852	Primary Predicate K220477	Reference Device K233391	Comparison
Indications for Use	The cCeLL - In vivo with Drop-In Robo is a confocal laser system with fiber optic probe 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. Upon intravenous administration and use of an ICG consistent with its approved labeling, the cCeLL - In vivo with Drop-In Robo is used to perform fluorescence angiography. Upon administration and use of ICG consistent with its approved labeling, the cCeLL - In vivo with Drop-In Robo is used to perform fluorescence imaging to support the visual assessment of vessels, blood flow, and related tissue perfusion. The Drop-In Robo is intended to provide visualization of organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures.	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, vessels and their organization or architecture. The Cellvizio® 100 Series System F400 is indicated for imaging blood flow in vascular areas, including microvasculature and capillaries. Upon intravenous administration and use of an ICG consistent with its approved labeling, the Cellvizio® 100 Series System F800 is used to perform fluorescence angiography. Upon interstitial administration and use of ICG consistent with its approved labeling, the Cellvizio® 100 Series System F800 is used to perform fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	The cCeLL - In vivo is an optic scanner probe placed in direct contact with tissue to create images of the internal microstructure of tissues and is indicated for use with indocyanine green (ICG) for fluorescence imaging as an aid in the visualization of vessels (micro- and macro-vasculature) blood flow in the cerebrovasculature before, during or after cranial diagnostic and therapeutic procedures, such as tumor biopsy and resection.	Similar

	Subject Device K251852	Primary Predicate K220477	Reference Device K233391	Comparison
		Upon administration and use of pafolacianine consistent with its approved labeling, the Cellvizio® 100 Series System F800 is used to perform fluorescence imaging of tissues that have taken up the drug. 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 AlveoFlex™ (-, -C) Confocal Miniprobes™ are intended to allow imaging of anatomical tracts, i.e., respiratory systems, accessed by an endoscope or endoscopic accessories. The CholangioFlex™ (-, -C) Confocal Miniprobes™ are intended to allow imaging of the upper gastrointestinal tract including biliary and pancreatic ducts, accessed by an endoscope or endoscopic accessories.		

	Subject Device K251852	Primary Predicate K220477	Reference Device K233391	Comparison
		The AQ-Flex™ 19 (-, -C) 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, F-C, and UHD, UHD-C) and UroFlex™ B (-, -C) 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, UHD 5-C) Confocal Miniprobes™ are intended to provide visualization of body cavities, organs, and canals during endoscopic and laparoscopic surgical procedures, including robot-assisted procedures. The CranioFlex™ (-, -C) Confocal Miniprobes™ are indicated to		

	Subject Device K251852	Primary Predicate K220477	Reference Device K233391	Comparison
		provide visualization within the central nervous system during cranial diagnostic and therapeutic procedures such as tumor biopsy and resection.		
Technological Characteristics	The cCeLL - In vivo with Drop-In Robo includes the following components and accessories: ● Main Unit (for NIR illumination and capturing) ● Drop-In Robo (for endoscope) The Drop-In Robo is intended to be connected to the Main Unit, which connects to the PC for image processing, as well as to the light source via optical fiber as the source of illumination to allow visualization of internal anatomy. Visualization and navigation is performed using NIR imaging for visual assessment and/or confirmation of vessels, blood flow or tissue perfusion is desired.	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.	The cCeLL - In vivo includes the following components and accessories: ● Main Unit (for NIR illumination and capturing) ● Pixection (for endoscope) ● Sterile Probe Sheath The Pixection is intended to be connected to the Main Unit, which connects to the PC for image processing, as well as to the light source via optical fiber as the source of illumination to allow visualization of internal anatomy. Visualization and navigation is performed using NIR imaging for visual assessment and/or confirmation of vessels, blood flow or tissue perfusion is desired.	Identical
Light Source	Laser	Laser	Laser	Identical
Excitation wavelength	775 nm	785 nm	775 nm	Similar
Detection bandwidth	813-850 nm	800-905 nm	813-850 nm	Similar

	Subject Device K251852	Primary Predicate K220477	Reference Device K233391	Comparison
Fluorescent Agent	Indocyanine Green (ICG)	Indocyanine Green (ICG), Pafolacianine	Indocyanine Green (ICG)	ICG only
Depth of Observation	44.6 µm	0-65 µm	48.9 µm	Similar
Field of View	500 µm × 500 µm	Circular, diameters of 240, 325, and 600 µm	500 µm × 500 µm	Similar
Lateral Resolution	2.19 µm	1–3.5 µm	2.46 µm	Similar
Fluorescence excitation power	Up to 3.5 mW	Up to 40 mW	Up to 3.5 mW	Similar

viii.   *Performance Testing*

The Drop-In Robo probe of the subject device have the same technical characteristics as Pixection probe of the reference device. Verification and validation testing demonstrated that the subject device conforms to the recognized safety standards, design input specifications.

Test	Test Method Summary	Results
Dose-response analysis	Using a small animal model, the fluorescence signal diffused along the blood vessels in the prostate area is observed immediately after ICG injection in the set concentration range, and the micro-vasculature and glandular structures are clearly identified with fluorescence images.	The study confirmed that the device effectively visualized micro-vasculature, and tissue perfusion is clearly laparoscopic surgery. PASS
Organ-specific analysis	A Drop-In Robo is applied to the surface of the prostate, seminal vesicle, bladder, liver, intestine, stomach, kidney and pancreas using an endoscopic simulation phantom and fluorescence imaging for each tissue is recorded.	The study confirmed that Fluorescence imaging was recorded for each tissue. PASS
Image quality	Comparison of the image brightness, contrast, FOV dimensions, and minimum resolvable structural diameters between Drop-In Robo and reference device.	Compared with the reference cCeLL – In vivo, the DUT showed higher mean brightness, higher mean contrast, and larger mean FOV values overall. PASS

Test	Test Method Summary	Results
Detection Linearity	To verify the device's accuracy and reliability in capturing fluorescence intensity, detection linearity was assessed by measuring optical power and brightness at various increments for both the reference and subject devices.	The detection linearity of the subject device was 0.997 (Variable optical power) and 0.993 (Variable brightness), all of which were greater than that of the reference device (0.993 Variable optical power, 0.981 Variable brightness). PASS
Geometric Distortion	To verify the device's accuracy and reliability in capturing fluorescence intensity with respect to geometric distortion, the power was measured using an optical power meter and radial distortion was calculated from the acquired image. Performance testing conducted with reference and subject devices.	The subject device's geometric distortion was 0.19 %, which is lower than that of the reference device (0.26 %). PASS
Dynamic Range	To verify the device's gradation performance in capturing fluorescence intensity across its dynamic range, optical power and brightness were set, fluorescent target removed, and the dynamic range was calculated using the acquired image. Performance testing conducted with reference and subject devices.	The subject device's dynamic range was 249, which is equal to that of the reference device (249). PASS
Illumination & Detection Uniformity	To verify the device's accuracy and reliability in capturing fluorescence intensity, illumination and detection uniformity, the average intensity of each fluorescent dot in the region of interest [diagnostic area] and the illumination uniformity were calculated using the acquired image. Performance testing conducted with reference and subject devices.	The subject device's illumination & detection uniformity was 88.42 %, which is greater than that of the reference device (74.04 %). PASS
Signal to Noise Ratio & Sensitivity	To verify the device's sensing ability in capturing fluorescence intensity, images were acquired and the signal to noise ratio (SNR) and sensitivity were calculated. Performance testing conducted with reference and subject devices.	The subject device's SNR was 18.44, which remains above a minimum acceptable level. PASS
Video Latency	To verify the device's dynamic vision capability in capturing fluorescence intensity, video latency was assessed by recording the initialization and stoppage of motion on the screen and calculating the latency. Performance testing conducted with reference and subject devices.	The subject device's video latency was 130 milliseconds, which remains below specified limit. PASS
Robotic Compatibility	To verify the compatibility of the device with robotic-assisted surgical environments, evaluations were conducted under both vertical and horizontal robotic grasping conditions. The test assessed whether the device-maintained image stability when manipulated by robotic instruments. Mean image displacement, a quantitative metric representing the average pixel shift between consecutive image frames, was calculated to validate stability. Performance testing was conducted with both reference and subject devices.	The mean image displacement of the subject device was 1.35 pixels (x-axis) and 2.66 pixels (y-axis) under vertical robotic grasping, and 0.63 pixels (x-axis) and 0.84 pixels (y-axis) under horizontal robotic grasping, all of which were lower than that of the reference device (7.33 pixels x-axis,

Test	Test Method Summary	Results
		16.72 pixels y-axis). PASS
Depth of Observation	To verify the device's depth of observation, a reflection target was used, and reflection intensity was measured across varying focal positions. The depth of observation was quantified by calculating the full width at half maximum (FWHM) of the resulting intensity profile. Performance testing was conducted with both reference and subject devices.	The subject device's depth of observation was 44.6 µm, which is lower than that of the reference device (48.9 µm). PASS
Field of View	To verify the device's field of view, a fluorescence calibration target containing an array of circular fluorescent patterns at fixed intervals was imaged. The horizontal (X-axis) and vertical (Y-axis) extents of the field of view were calculated based on the number and spacing of visible patterns in each direction. Performance testing was conducted with both reference and subject devices.	The subject device's FOV was 503 µm × 505 µm, which falls within the acceptable range of (500 ± 10%) µm × (500 ± 10%) µm. PASS
Lateral Resolution	To verify the device's lateral resolution, a USAF-1951 resolution target was imaged, and the modulation transfer function (MTF) was calculated based on the contrast response of the target's line pairs. The lateral resolution was determined from the spatial frequency at which the MTF dropped to a predefined threshold. Performance testing was conducted with both reference and subject devices.	The subject device's lateral resolution was 2.19 µm, which is lower than that of the reference device (2.46 µm). PASS
Electrical Safety / EMC	IEC 60601-1:2005/AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-2:2014 +A1:2020 CSV, Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Electromagnetic Compatibility	PASS
Software / Cybersecurity (Enhanced Level)	FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" issued June 14, 2023. FDA guidance's Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Postmarket Management of Cybersecurity in Medical Devices.	PASS
Biocompatibility	Per FDA's Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", the reusable Drop-In Robo is categorized as an external communicating device in contact with tissue/bone/dentin for <24 hours.	Biocompatibility testing in accordance with FDA's biocompatibility guidance demonstrated that the patient-contacting components are biocompatible.

Test	Test Method Summary	Results
	The following biocompatibility endpoints were evaluated: Cytotoxicity Sensitization Intracutaneous reactivity Acute system toxicity Material medicated pyrogenicity Endotoxin	PASS
Sterility / Reprocessing	ISO 11135:2014 + Amd1:2018 Sterilization of health care product – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices ISO 11737-1: Sterilization of health care products - Microbiological methods- Part 1: Determination of a population of microorganisms on product ISO 11737-2: Sterilization of medical devices - Microbiological methods- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process FDA's Guidance for Industry and FDA Staff, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" issued March 17, 2015	Sterilization and reprocessing testing of the Drop-In Robo demonstrated the device is and can remain sterile and functional for the documented reprocessing. PASS

ix. Conclusion

The subject device, *cCeLL – In vivo with Drop-In Robo*, shares the *same component, design, fundamental technology, and operating principle* as the previously cleared reference device *cCeLL – In vivo (K233391)*. The only difference lies in the *Drop-In Robo* probe, which has been modified to enable compatibility with robotic surgical instruments via drop-in configuration. There are *no changes to the optical, electronic, or mechanical core components* of the Main Unit compared to the cleared device in K233391.

The *cCeLL – In vivo with Drop-In Robo* system is similar to the *Cellvizio 100 Series System with Confocal Miniprobes* System (cleared via K220477) including the intended use of the system with the approved infrared contrast agents, ICG injection. Both devices are 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.

Based on the similarities of the indications for use, device design, principles of operation, technological characteristics and the results of the non-clinical performance testing, the subject device, cCeLL - In vivo with Drop-In Robo, is substantially equivalent to the legally marketed predicate device and does not raise new concerns of safety and effectiveness.