August 21, 2024

VPIX Medical, Inc.
% Dawn N. Norman, M.S.
Partner
MRC Global, LLC
9085 E. Mineral Circle, Suite 110
Centennial, CO 80112

Re: K233391
Trade/Device Name: cCeLL - In vivo
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG, OWN
Dated: July 18, 2024
Received: July 22, 2024

Dear Dawn Norman:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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.

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,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2024.08.21 15:25:30 -04'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices

OHT5: Office of Neurological and
Physical Medicine 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)*
K233391

Device Name
cCeLL - In vivo

Indications for Use *(Describe)*
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.

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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K233391 510(k) Summary

i. Submitter Information

Submitter:	VPIX Medical, Inc. 774, Gyeryong-ro, Jung-gu Daejeon, 34873 Republic of Korea
Contact Person:	Kyungmin Hwang, President
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Official Correspondent:	Dawn Norman, MS
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Phone:	01-618-604-3064

Date Prepared:	August 17, 2024

ii. Device Name

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)

iii. Predicate Devices

510(k) Number:	K180146
Proprietary Name:	KARL STORZ ICG Imaging System
Manufacturer:	KARL STORZ Endoscopy-America, 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, OWN

iv. Device Description

The cCeLL - In vivo is used to provide real-time endoscopic images of near-infrared (NIR) indocyanine green (ICG) dye fluorescence during minimally invasive, neurosurgery in adults.

The overall system includes a 6 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 intended for maintaining a sterile barrier between the subject device and the patient. The cCeLL - In vivo can be used with any medical grade high definition (HD) monitor with a DVI-D or RGB input. The patient contacting components contact tissue or bone with a duration of less than 24 hours.

v. Principle of Operation / Mechanism of Action

This product irradiates the tissue with a laser by contacting the probe to the suspected tumor site of a patient injected with indocyanine green. 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 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.

vii. Summary of Substantial Equivalence

The similarities between subject device and predicate device are as follows:

Both devices provide images of NIR Indocyanine green (ICG) dye fluorescence during minimally invasive, neurosurgery in adults.

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 also provides fluorescence during plastic, micro- and reconstructive surgical procedures in adults and pediatric populations. The predicate allows use of a medical grade HD monitor with 3G-SDI input. The predicate device is supplied with an ICG kit while the subject device is not.

Substantial Equivalence Table:

	Subject Device	Predicate Device	Comparison
510(k) Number	K233391	K180146	N/A
Device Identification	Trade Name: cCeLL - In vivo Classification Name: Neurological Endoscope	Trade Name: KARL STORZ ICG Imaging System Classification Name: Neurological Endoscope	N/A
Product Code	GWG, OWN	GWG, OWN	Identical
Regulation	21 CFR 876.1480 (Neurological Endoscope)	21 CFR 876.1480 (Neurological Endoscope)	Identical
Device Description	The cCeLL - In vivo is used to provide real-time high-definition (HD) endoscopic images of near-infrared (NIR) indocyanine green (ICG) dye fluorescence during minimally invasive, neurosurgery in adults. The overall system includes a 6 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 KARL STORZ ICG Imaging System is used to provide real-time high-definition (HD) endoscopic or telescopic images of visible (VIS) and near-infrared (NIR) indocyanine green (ICG) dye fluorescence during minimally invasive, neuro- and endonasal skull base surgery as well as plastic, micro- and reconstructive surgical procedures in general and pediatric populations. The overall system includes a 4mm HOPKINS ICG/NIR Endoscope (0°, 30° or 45°) for use in neuro- and endonasal skull base surgery, a 5mm & 10mm HOPKINS ICG/NIR Endoscope (0° or 30°) for use in minimally invasive procedures and a VITOM II ICG/NIR Telescope for use in plastic, micro- and reconstructive surgical procedures for VIS and NIR illumination and imaging, a light source with foot switch for emission of VIS and NIR illumination, a color video camera head capable of capturing both VIS and NIR imaging, and a KARL STORZ ICG Kit. Additional accessories used with the KARL STORZ ICG Imaging System include two standards fiber-optic light cables for transmission of VIS and NIR light and the Image1 S Camera Control Unit (CCU).	**Similarities** Both devices provide HD images of NIR Indocyanine green (ICG) dye fluorescence during minimally invasive, neuro- and endonasal skull base surgery in adults. Both can be used with any medical grade HD monitor with a DVI-D input. **Differences** The predicate also provides fluorescence during plastic, micro- and reconstructive surgical procedures in pediatric populations. The predicate allows use of a medical grade HD monitor with 3G-SDI input.

	Subject Device	Predicate Device	Comparison
	The cCeLL - In vivo can be used with any medical grade HD monitor with a DVI-D or RGB input.	The KARL STORZ ICG Imaging System can be used with any medical grade HD monitor with a DVI-D or 3G-SDI input.	The predicate device is supplied with an ICG kit while the subject device is not.
Intended Use	The cCeLL - In vivo is intended to provide real-time near-infrared fluorescence imaging.	The KARL STORZ ICG Imaging System is intended to provide real-time visible and near-infrared fluorescence imaging.	Identical except the predicate provides visible fluorescence imaging.
Indications for Use	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.	The KARL STORZ Endoscopic ICG System enables surgeons to perform minimally invasive surgery using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion, or at least one of the major extra-hepatic bile ducts (cystic duct, common bile duct and common hepatic duct), using near infrared imaging. Fluorescence imaging of biliary ducts with the KARL STORZ Endoscopic ICG System is intended for use with standard of care white light and, when indicated, intraoperative cholangiography. The device is not intended for standalone use for biliary duct visualization. Additionally, the KARL STORZ Endoscopic ICG System enables surgeon to perform minimally invasive cranial neurosurgery in adults and pediatrics and endonasal skull base surgery in adults and pediatrics > 6 years of age using standard endoscopic visible light as well as visual assessment of vessels, blood flow and related tissue perfusion using near infrared imaging. The KARL STORZ VITOM II ICG System is intended for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of	**Similarities** Both use HD images of NIR Indocyanine green (ICG) dye fluorescence during minimally invasive, neuro- and endonasal skull base surgery in adults. Both can be used with any medical grade HD monitor with a DVI-D input. **Differences** The predicate is indicated for pediatrics cranial neurosurgery and endonasal skull base surgery in adults and pediatrics > 6 years of age. The predicate has multiple light and visualization options. The predicate also

	Subject Device	Predicate Device	Comparison
		tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures. The VITOM II ICG System is intended to provide a magnified view of the surgical field in standard white light.	provides fluorescence during plastic, micro- and reconstructive surgical procedures in general and pediatric populations. The predicate allows use of a medical grade HD monitor with 3G-SDI input.
Technological Characteristics	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.	The KARL STORZ ICG Imaging System includes the following components and accessories: ● 4mm, 5mm & 10mm HOPKINS ICG/NIR Endoscopes ● VITOM II ICG Telescope ● Camera Head (H3Z-FI) ● Fiber optic Light Cables ● Light Source ● Image1 S CCU The endoscopes/telescope are intended to be connected to the optical coupler of the camera head, which connects to the CCU for image processing, as well as to the light source via compatible light cable as the source of illumination to allow visualization of internal anatomy. Visualization and navigation is performed initially using VIS imaging. NIR imaging is selected when visual assessment and/or confirmation of vessels, blood flow or tissue perfusion is desired.	**Similarities** Both devices use a camera and optical fiber light source to process images. **Differences** The predicate uses VIS while the subject device uses NIR for Visualization and navigation.

viii. Performance Testing

Verification and validation testing demonstrated that the subject device conforms to the recognized safety standards, design input specifications and intended use consistent with the predicate device.

Test	Test Method Summary	Results
Image Sensitivity Analysis	Validate the device's ability to visualize cerebral microstructures and vascular systems, including tumor tissue, surrounding normal tissue, blood vessels using clinically relevant ICG concentrations in a small animal model.	The study confirmed that the device effectively visualized cerebral microstructures and vascular systems across a range of clinically relevant ICG concentrations. PASS
Image Comparison Analysis	Comparison of the fluorescence signal between the subject and predicate device, following ICG injection in a small animal model, was conducted to determine if the subject device performs equivalently to the predicate device in visualizing vessels of various sizes and changes in blood flow.	The study confirmed that the subject device can visualize vessels of various sizes and changes in blood flow with image quality comparable to the predicate device, as assessed across users with a range of experience. PASS
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 predicate and subject devices.	The detection linearity test demonstrated equivalent performance to the predicate device. 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 the predicate and subject devices.	The geometric distortion test demonstrated equivalent performance to the predicate device. 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 the predicate and subject devices.	The dynamic range test demonstrated equivalent performance to the predicate device. 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	Testing measuring illumination and detection uniformity demonstrated equivalent performance to the predicate device. PASS

Test	Test Method Summary	Results
	illumination uniformity were calculated using the acquired image. Performance testing conducted with the predicate and subject devices.	
SNR & 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 the predicate and subject devices.	SNR & sensitivity test demonstrated equivalent performance to the predicate device. PASS
Video Latency	To verify the device's dynamic vision capability in capturing fluorescence intensity, video latency was assessed by recoding the initialization and stoppage of motion on the screen and calculating the latency. Performance testing conducted with the predicate and subject devices.	The test results demonstrated equivalent performance to the predicate device. PASS
Sterile Probe Sheath Tear Resistance	To verify the robustness of SPS (Sterile Probe Sheath) tear resistance of the SPS was tested for breaking strength at different join interfaces on aged samples.	The test resutls demonstrated that the SPS can withstand forces greater than those expected during clinical use. PASS
Electrical Safety / EMC	IEC 60601-1:2005 + A1:2012 + A2:2021 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance IEC 60601-1-2 : 2014 + A1:2020, 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 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 single use Sterile Probe Sheath (SPS) 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. PASS

Test	Test Method Summary	Results
	The following biocompatibility endpoints were evaluated: Cytotoxicity Sensitization Intracutaneous reactivity Acute systemic toxicity Material medicated pyrogenicity Hemocompatibility (indirect) Neurotoxicity	
Sterility / Shelf Life	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 ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices ISO 11607–1:2019 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems were used to validate the shelf life.	Sterilization and shelf-life testing of the Sterile Probe Sheath (SPS) demonstrated the device is and can remain sterile and functional for the documented shelf life. PASS

ix. Conclusion

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, is substantially equivalent to the legally marketed predicate device and does not raise new concerns of safety and effectiveness.