November 25, 2019

Medtronic
% Ray Kelly
Consultant
Arazy Group Consultants Inc.
3422 Leonardo Ln
New Smyrna Beach, Florida 32168

Re: K191851
Trade/Device Name: VS3-IR
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN, GCJ
Dated: October 25, 2019
Received: October 28, 2019

Dear Ray Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Purva Pandya
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191851

Device Name

VS3-IR

Upon intravenous administration and use of an ICG consistent with its approved label, the Iridium Module of the VS3-IR System is used to perform intraoperative fluorescence angiography.

Upon interstitial administration and use of ICG consistent with its approved label, the Endoscope configuration of the VS3-IR System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

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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510(k) Summary
K191851

I. SUBMITTER

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Date Prepared: November 25, 2019

II. DEVICE

Name of Device: VS3-IR
Common or Usual Name: Confocal Optical Imaging
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: II
Product Code: OWN

III. PREDICATE DEVICE

PINPOINT Endoscopic Fluorescence Imaging System, K182606
This predicate has not been subject to a design-related recall.
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: II
Product Code: OWN
Reference Device: VS3-IR, K183453

IV. DEVICE DESCRIPTION

Clearance was originally given for the Visionsense Stereoscopic Vision System (VSII) in K073279, K081102, K082667, and K082355. Clearance was given for a 3D High Definition version of the VSII System called the VS3 Stereoscopic High Definition Vision System (VS3) in K123467, K131434, K141002. Clearance included the HD3D Camera, Laser Light Source (LLS), VS3 3D Endoscope, Camera Control Unit (CCU), Display Monitor, Xenon Light Source, and Endoscopic Light Cable.

Clearance was given for an iridium version of the VS3 system called the "VS3-IR System" in K150018 and K152204. This system introduced an iridium miniature microscope in K150018 and an iridium endoscope in K152204. The cleared system added a Light Integrator and an ICG Kit. The VS3-IR utilizes the VS3 system with a special Miniature Microscope (MMS) that is positioned 20cm to 45cm above the patient during the surgical procedure. The VS3-IR can also be used with an Iridium Endoscope to perform minimally invasive procedures. The VS3-IR is designed to work with Indocyanine Green (ICG) which is an IR fluorescence imaging agent and is supplied in the "VS3-IR Fluorescence ICG Kit". Each cleared "VS3-IR Fluorescence ICG Kit" contains six 25mg vials of sterile ICG imaging agent and six 10ml vials of sterile Water for Injection. ICG is a sterile, water soluble, tricarbocyanine dye with a peak spectral absorption at 785nm or 805nm in blood plasma or blood. ICG contains not more than 5.0% sodium iodide. ICG is to be administered intravenously. The sterile Water for Injection provided with the ICG, pH of 5.0 to 7.0, is used to dissolve the ICG. Before injection of ICG for each patient's imaging procedure, the ICG must be reconstituted using the sterile Water for Injection. ICG in blood has excitation at 785nm or 805nm. The VS3-IR system provides excitation light to the surgical field to excite the dye molecules, captures emission from the dye using an IR camera and measures the fluorescence signal intensity. The system enables high definition imaging for both fluorescence and visible light imaging, with real-time overlay of fluorescence and visible light images for display on the monitor. The system permits recording surgical procedures, storing them on removable storage devices, and playing the procedures back.

Clearance was given for adding three working channels to the VS3 in K153548 and the accessory "Trans-Anal Introducer" was cleared in K171208.

The VS3-IR system (805nm) was cleared for adding the excitation wavelength of 785nm in K183453. The "Indication for Use" cleared in K183453 is:

"The 3D Endoscope Module of the VS3-IR System is intended for viewing internal surgical sites during general surgical procedures, for use in visualization of ventricles and structures within the brain during neurological surgical procedures, viewing internal surgical sites during anterior and posterior spinal procedures, such as nucleotomy, discectomy, and foraminotomy, and shoulder and knee arthroscopic procedures.

The MMS configuration of the Iridium Module of the VS3-IR System is intended for capturing and viewing fluorescent images for the visual assessment of blood flow, as an adjunctive method for the evaluation of tissue perfusion, and related tissue-transfer circulation in tissue and free flaps used in plastic, micro- and reconstructive surgical procedures.

The Endoscope configuration of the Iridium Module of the VS3-IR System is intended to provide real-time endoscopic visible and near infrared fluorescence imaging. Iridium Endoscope enables surgeons to perform routine visible light endoscopic procedures as well as further visually assess vessels, blood flow and related tissue perfusion with near infrared imaging during minimally invasive surgery."

The present 510(k) application K191851 provides clearance of the VS3-IR system for expanding the scope of indications to include usage in the lymphatic system with use of an ICG consistent with its approved label. As the VS3-IR may be still be co-packaged with the currently cleared "VS3-IR Fluorescence ICG Kit" within the indications for use cleared under prior 510(k) clearance, the device labeling will instruct not using the currently cleared "VS3-IR Fluorescence ICG Kit" for use in the lymphatic system when the VS3-IR is intended for this indication and associated administration modality. This clearance enables the VS3-IR system to be also cleared for use in the indications in Section V with use of an ICG consistent with its approved label, including in terms of indications and associated administration modalities.

Use of ICG consistent with its approved label may refer to either the VS3 Iridium ICG kit cleared through the reference device (K183453: VS3-IR) or to use an ICG consistent with its approved label for lymphatic mapping, no copackaging is being introduced for indications involving lymphatic mapping.

V. INDICATIONS FOR USE

Upon intravenous administration and use of an ICG consistent with its approved label, the Iridium Module of the VS3-IR System is used to perform intraoperative fluorescence angiography.

Upon interstitial administration and use of ICG consistent with its approved label, the Endoscope configuration of the VS3-IR System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Subject Device K191851 (VS3-IR)	Predícate Device K182606 (PINPOINT)
Upon intravenous administration and use of an ICG consistent with its approved label, the Iridium Module of the VS3-IR System is used to perform intraoperative fluorescence angiography.	Upon intravenous administration of TRADENAME (ICG drug product), the PINPOINT Endoscopic Fluorescence Imaging System is used with TRADENAME to perform intraoperative fluorescence angiography, and it is also indicated for use in fluorescence imaging of biliary ducts, and when indicated, during intraoperative cholangiography.
Upon interstitial administration and use of ICG consistent with its approved label, the Endoscope configuration of the VS3-IR System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.	Upon interstitial administration of TRADENAME (ICG drug product), the PINPOINT System is used to perform intraoperative fluorescence imaging and visualization of the lymphatic system, including lymphatic vessels and lymph nodes.

Design Attributes		Subject Device K191851 (VS3-IR)	Predícate Device K182606 (PINPOINT)
Sterilization		Steam Autoclave	Steam Autoclave
Imaging Head		Silicon Image Sensor in the Camera	Silicon Image Sensor in the Camera
Light Source		Infrared Laser	Infrared Laser
Imaging Agent		IR fluorescence dye (i.e. Indocyanine Green-ICG)	IR fluorescence dye (i.e. Indocyanine Green-ICG)
Excitation Light Source Wavelength	VS3-IR-Endoscope	785nm, 805nm	805nm
	VS3-IR-MMS	785nm, 805nm	NA
Light Source for Visible Image	VS3-IR-Endoscope	Xenon up to 500mW	Mercury
	VS3-IR-MMS	LED	NA
Spectral Bandwidth of Visible Light Source	VS3-IR-Endoscope	400nm – 700nm	400nm – 700nm
	VS3-IR-MMS	400nm – 700nm	NA
Imaging Distance	VS3-IR-Endoscope	7mm to 70mm	7mm to 70mm
	VS3-IR-MMS	20cm to 45cm	NA
Excitation Light Source Intensity and Maximum Light Intensity	VS3-IR-Endoscope	54mW/cm^2 at 2cm; 500mW total output	Pinpoint IR light source is pulsed
	VS3-IR-MMS	6mW/cm^2 at 40cm; Max of 47mW/cm^2	NA
Field of View	VS3-IR-Endoscope	70º to 95º	70º to 95º
	VS3-IR-MMS	55º	NA
Scope Length	VS3-IR-Endoscope	300 mm	300 mm
	VS3-IR-MMS	NA	NA
Scope Diameter	VS3-IR-Endoscope	5.5mm, 10mm	5.5mm, 10mm
	VS3-IR-MMS	NA	NA
Angles of View	VS3-IR-Endoscope	0º, 30º	0º, 30º
	VS3-IR-MMS	NA	NA
Imaging	VS3-IR-Endoscope	Fluorescent and White Light Imaging	Fluorescent and White Light Imaging
	VS3-IR-MMS	Fluorescent and White Light Imaging	NA
Emission Band	VS3-IR-Endoscope	800nm to 850nm	825nm to 850nm
	VS3-IR-MMS	800nm to 850nm	NA
Emission Capture		IR camera	IR camera
Display both Visible and IR images		Yes	Yes
Working Length-Endoscope		5mm – 30cm	10mm – 33cm

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

BIOCOMPATIBILITY:
Biocompatibility evaluation was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.
Patient contacting components (3D camera, 3D endoscopes, and VS3-IR-Endoscopes) of the VS3-IR System are constructed of Stainless Steel, Aluminum, and Glass components, which are the same materials that are used in the 3D camera, 3D endoscope, and VS3-IR-Endoscope originally cleared in K152204, K131434, K123467, K183453.
The Stainless Steel, Aluminum, and Glass materials that are used to construct the 3D camera, 3D endoscope, and VS3-IR-Endoscopes of the VS3-IR System are processed and manufactured in the same manner as the Stainless Steel, Aluminum, and Glass that are used in the predicate 3D camera, 3D endoscope, and VS3-IR-Endoscope originally cleared in K152204, K131434, K123467, K183453.
The device is a surface-contacting device in contact with mucosal membranes. The contact duration is limited exposure (contact is up to 24 hours).

ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY (EMC):
Electrical safety and EMC testing were conducted on the VS3-IR System. The system complies with the IEC 60601-1, IEC 60601-2-18, IEC 60601-1-6, and IEC 60825-1 standards for safety and the IEC 60601-1-2 standard for EMC.

SOFTWARE VERIFICATION AND VALIDATION:
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern.

CYBERSECURITY:
The VS3-IR System is a locked-down stand-alone device. The device is not connected to a network and is not accessible in any way other than through the device's user interface. The operating system on the device is fully locked down and all user access to the OS is disabled. USB ports are only accessible for exporting videos and reading configuration data. The system cannot be booted from USB and spurious or malicious software cannot be run from USB. Direct access to USB file system is prevented due to OS lock-down.

VIII. CONCLUSIONS
Through performance testing the subject device has demonstrated substantial equivalence to the predicate.