October 28, 2022

Visionsense Ltd.
Guy Wroclawski
Senior Regulatory Affairs Specialist
20 Hamagshimim St.
Petach Tikva, Hamerkaz, Central District 4934829
Israel

Re: K223020
Trade/Device Name: VS3-Iridium System (VS3-IR)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: September 28, 2022
Received: September 29, 2022

Dear Guy Wroclawski:

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,

Colin Kejing Chen
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223020

Device Name
VS3-Iridium System (VS3-IR)

Indications for Use *(Describe)*
The VS3-Iridium System is intended to provide real-time visible and near infrared fluorescence imaging in both open and minimally invasive procedures.

Upon intravenous administration and use of an ICG consistent with its approved labeling, the VS3-Iridium System is used to perform fluorescence imaging visualization of vessels, blood flow and tissue perfusion before during and after general minimally invasive surgical procedures and plastic, micro-, reconstructive surgeries.

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

Upon administration and use of pafolacianine consistent with its approved labeling, the VS3-Iridium 785 nm System is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

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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K223020

510(k) Summary

VS3-Iridium System (VS3-IR)

The contents of the 510(k) Summary have been provided in conformance with 21 CFR 807.92.

1. Submitter

510(k) Summary:

Date summary prepared: October 19, 2022

510(k) Submitter/Holder:

Visionsense, Ltd.
20 Hamagshimim St.
Petach Tikva, Hamerkaz
4934829 Israel

Contact Person:
Guy Wroclawski
Senior Regulatory Affairs Specialist
Medtronic, Visualization
Telephone: (972) 50-204-9052
Fax: (972) 3-924-4335
Email: guy.wroclawski@medtronic.com

2. Subject Device

Trade Name:	VS3-Iridium System (VS3-IR)
VS3-IR system configuration	**Camera** (K150018, K152204, K183453, K191851, K210265) **Laser Light Source** (LLS) (K150018, K152204, K183453, K191851, K210265) **VS3-IR-MMS** (K150018, K152204, K183453, K191851, K210265) **VS3-IR-Endoscope** (K152204, K183453, K191851) **CCU** (K150018, K152204, K183453, K191851, K210265) **Display Monitor** (K150018, K152204, K183453, K191851, K210265) **Xenon Light Source** (K150018, K152204, K183453, K191851, K210265) **Endoscopic Light Cable** (K150018, K152204, K183453, K191851, K210265) **Light Integrator** (K150018, K152204, K183453, K191851, K210265)
Common Name:	Near-IR visualization system

Classification Name:	Endoscope and accessories (21 CFR 876.1500)
Product Code:	OWN
Regulatory Class:	II

3. Predicate Device

Trade Name:	VS3-Iridium System (VS3-IR)
VS3-IR system configuration	**Camera** (K150018, K152204, K183453, K191851, K210265) **Laser Light Source** (LLS) (K150018, K152204, K183453, K191851, K210265) **VS3-IR-MMS** (K150018, K152204, K183453, K191851, K210265) **VS3-IR-Endoscope** (K152204, K183453, K191851) **CCU** (K150018, K152204, K183453, K191851, K210265) **Display Monitor** (K150018, K152204, K183453, K191851, K210265) **Xenon Light Source** (K150018, K152204, K183453, K191851, K210265) **Endoscopic Light Cable** (K150018, K152204, K183453, K191851, K210265) **Light Integrator** (K150018, K152204, K183453, K191851, K210265) **ICG Kit** (K150018, K152204, K183453, K191851)
510(k) Number:	There are five predicate 510(k) submissions for this 510(k). A description of each 510(k) is provided along with each 510(k) submission number. K150018 (cleared the MMS configuration, 805 nm wavelength plus the VS3-IR ICG Kit) K152204 (cleared the endoscopic configuration, 805 nm wavelength) K183453 (cleared the 785 nm wavelength, both MMS and endoscopic) K191851 (cleared the lymphatic visualization indication, both 785 nm and 805 nm) K210265 (cleared the 785 nm system for use with pafolacianine)
Manufacturer:	Visionsense, Ltd.

4. Device Description

The VS3-Iridium System is an advanced stereoscopic visualization system made up of a combination of hardware and software to provide high definition visible and near infrared (IR) fluorescent imaging. The visualization system can incorporate an endoscope for minimally invasive surgical procedures and a microscope positioned above the patient during open surgical procedures.

The VS3-Iridium System including the endoscope and the microscope is designed to work with an approved infrared dye (Indocyanine green (ICG) or pafolacianine sodium injection or pafolacianine). ICG may be excited at excitation at either 785 or 805 nm, and pafolacianine is excited only by the 785 nm wavelength. The principle of operation is the same for both infrared dyes. That is, the VS3-Iridium System provides excitation light to the surgical field to excite the dye molecules and captures emission from the dye using an IR camera, enabling qualitative and quantitative measurement of the IR intensity. Near IR fluorescence imaging with ICG permits the system to visualize blood flow and related tissue circulation, of lymphatic flow.

The VS3-Iridium System allows the capture of normal (white) light image in parallel with the fluorescence IR image and displays both to the surgeon to provide a view of the anatomy. In addition, the VS3-Iridium System permits recording surgical procedures, storing them on removable storage devices, and replaying the procedures.

This special 510(k) premarket notification is to re-frame the indications for use statement to be consistent with specific indications of legally marketed ICG products, eliminating the need for the VS3-Iridium Fluorescence ICG Kit.

5. Indications for Use

The VS3-Iridium System is intended to provide real-time visible and near infrared fluorescence imaging in both open and minimally invasive procedures.

Upon intravenous administration and use of an ICG consistent with its approved labeling, the VS3-Iridium System is used to perform fluorescence imaging visualization of vessels, blood flow and tissue perfusion before, during, and after general minimally invasive surgical procedures and plastic, micro-, reconstructive surgeries.

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

Upon administration and use of pafolacianine consistent with its approved labeling, the VS3-Iridium 785 nm System is used to perform intraoperative fluorescence imaging of tissues that have taken up the drug.

6. Difference in indications for use statements

The proposed changes in the indications for use statement are required to reflect the previous discontinuation of the 3D module and associated endoscopes, streamline the ICG-related indications and reflect that these indications are derived from approved ICG drug labeling.

This is a simple statement of product functionality that has always been present and does not represent any new use for the system. Therefore, there are no questions related to safety or effectiveness of the device when used as labeled, and the change is not considered a critical change to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device.

7. Technological Characteristics

Characteristic	Currently cleared VS3-Iridium System (Predicate)	VS3-Iridium System (Proposed Device)	Differences between the Subject and Predicate devices
Basic principle	The VS3-Iridium System allows the capture of normal (white) light images in parallel with the fluorescence IR image and displays both to the surgeon to provide a view of the anatomy.	The VS3-Iridium System allows the capture of normal (white) light images in parallel with the fluorescence IR image and displays both to the surgeon to provide a view of the anatomy.	None
Imaging	Fluorescent and White Light Imaging	Fluorescent and White Light Imaging	None
Imaging Head	Silicon Image Sensor in the Camera	Silicon Image Sensor in the Camera	None
Light Source	Infrared Laser	Infrared Laser	None
Excitation Light Source Wavelength VS3-IR-	785nm or 805 nm	785nm or 805 nm	None
Light Source for Visible Image VS3-IR-	LED	LED	None
Spectral Bandwidth of Visible Light Source	400nm – 700 nm	400nm – 700 nm	None
VS3-IR-MMS Position	20cm to 45cm above patient	20cm to 45cm above patient	None
Laparoscopes	Yes	Yes	None
Patient Contacting Materials	The Endoscopes and Cable used for minimally invasive procedure have direct patient contact. The components used for open surgical imaging do not directly contact the patient.	The Endoscopes and Cable used for minimally invasive procedure have direct patient contact. The components used for open surgical imaging do not directly contact the patient	None
Excitation Light Source Intensity	6 mW/cm2 at 40 cm Max of 47 mW/cm2	6 mW/cm2 at 40 cm Max of 47 mW/cm2	None

Characteristic	Currently cleared VS3-Iridium System (Predicate)	VS3-Iridium System (Proposed Device)	Differences between the Subject and Predicate devices
and Maximum Light Intensity			
Emission Capture	IR camera	IR camera	None
Display both Visible and IR images	Yes	Yes	None

8. Comparison of Technological Characteristics with the Predicate Device

There are no changes in technological characteristics in the visualization system hardware, software, or accessories associated with the labeling changes.

The only change in the system configuration is to obsolete the VS3-IR ICG Kit, which is no longer relevant for the system.

9. Performance Data

No performance data are needed to support the modified indications for use. As noted above, there are no technological changes associated with the proposed labeling changes. Additionally, no new surgical procedures or tissue types are being referenced in the modified indications for use.

10. Conclusions

The proposed VS3-Iridium System is the same or similar to the VS3-Iridium System legally marketed under the previously cleared 510(k) clearances.