November 22, 2021

Visionsense Ltd.
Nancy Sauer
Regulatory Director
20 Hamagshimim St.
Petach Tikva, Hamerkaz, Central District 4934829
Israel

Re: K210265
Trade/Device Name: VS3 Iridium Sytem
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: OWN
Dated: August 4, 2021
Received: August 5, 2021

Dear Nancy Sauer:

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,

for

Neil R. P. Ogden
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)*

K210265

Device Name
VS3 Iridium System

Indications for Use *(Describe)*

Upon intravenous administration and use of an ICG consistent with its approved labeling, 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 labeling, 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 administration and use of pafolacianine consistent with its approved labeling, the VS3-IR 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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K210265

510(k) Summary

VS3 Iridium System

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

1. Submitter

510(k) Submitter: Visionsense Ltd. (Medtronic)
20 Hamagshimim Street
Petach Tikva, Hamerkaz
4934829 Israel

Contact Person: Nancy Sauer, Regulatory Director Lung Health and Visualization

Phone: 720-361-5290
Email: nancy.k.sauer@medtronic.com

Date Prepared: August 20, 2021

2. Subject Device

Trade Name : VS3 Iridium System
Common Name: Confocal Optical Imaging
Classification Name: Endoscope and Accessories
21 CFR Part 876.1500
Product code: OWN
Regulatory Class: II
Manufacturer: Visionsense Ltd. (Medtronic)

3. Predicate Devices

Predicate Device Trade Name	**VS3 Iridium System (Primary Predicate)**	**VS3 Iridium System (Secondary Predicate)**
510(k) Number	K183453	K191851
510(k) Holder	Visionsense Ltd. (Medtronic)	Visionsense Ltd. (Medtronic)
Classification Name	Confocal Optical Imaging	Confocal Optical Imaging
Product Code and Regulation	OWN- 21 CFR Part 876.1500	OWN- 21 CFR Part 876.1500
Classification	II	II

The predicate devices have not been subject to a design-related recall.

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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 Traditional 510(k) premarket notification is to expand the indication for use statement to include the additional cleared infrared dye, pafolacianine sodium injection, for use with infrared imaging.

5. Intended Use

The VS3 Iridium System is intended for viewing anatomical structures during invasive surgery and for viewing fluorescent images for the visual assessment of blood flow and lymphatic flow. The unit is indicated for viewing internal surgical sites during general surgical procedures. It provides an adjunctive method for the evaluation of tissue perfusion and related tissue transfer circulation in tissue and free flaps used in general, plastic, micro-and reconstructive surgical procedures. It also enables the identification of functional lymphatic vessel, and/or lymph nodes. The VS3 Iridium System is also intended to visualize tissues that have taken up the pafolacianine during procedures that are consistent with the approved labeling of that dye.

6. Indications for Use

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

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7. Summary of Characteristics Compared to Predicate Device

The VS3 Iridium System has the same performance as the predicate device which is the equivalent VS3 Iridium System. This 510(k) expands the indication for use to include an additional fluorescent dye, pafolacianine for use with the system.

8. Performance Data

There are no performance standards or special controls developed for confocal optical imaging systems. The expansion of the indication of the subject device does not change the biocompatibility, electrical safety, electromagnetic compatibility, or sterilization from the previous clearance in K191851. Software validation data was provided for minor included software updates.

9. Clinical Data

Performance of the VS3 Iridium System with pafolacianine was demonstrated through a phase 3, randomized, single dose, open-label study (clinicaltrials.gov study NCT03180307). The study was designed to investigate the safety and efficacy of OTL38 injection (OTL38) for intra-operative imaging of folate receptor positive ovarian cancer in females 18 years old or older. The proportion of patients with at least one confirmed FR+ ovarian cancer evaluable lesion detected by the combination of OTL38 and NIR fluorescent light but not under normal light or palpation was 33% (95% CI [0.243, 0.427]). Safety results related to the VS3 Iridium System imaging subgroup (n=127) showed that there were 0 treatment-emergent adverse device effects (TEAE). The ability of OTL38 coupled with the Visionsense VS3 Iridium system to detect evaluable lesions in 33% of patients coupled with the lack of TEAE demonstrate that the VS3 Iridium System is safe to use in conjunction with the OTL38 drug.

10. Conclusion

The VS3 Iridium System has the same general intended use, materials, design, energy source, principle of operation and performance as the primary predicate device, VS3 Iridium System cleared under 510(k) K183453 and the secondary predicate device, VS3 Iridium System cleared under 510(k) K191851. Therefore, the VS3 Iridium System is found to be substantially equivalent to the legally marketed predicate device, VS3 Iridium System (K183453 and K191851) as the differences do not raise new questions of safety and efficacy.