



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Visionsense Ltd.  
% Mr. Raymond Kelly  
Licensale Incorporated  
57 Lazy Brook Road  
Monroe, Connecticut 06468

October 28, 2015

Re: K152204  
Trade/Device Name: VS3-IR  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: OWN, GCJ, HRX, GWG  
Dated: August 5, 2015  
Received: August 6, 2015

Dear Mr. 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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joshua C. Nipper -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152204

Device Name

VS3-IR

Indications for Use (Describe)

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 infra-red imaging during minimally invasive surgery.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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**510(k) Summary  
Visionsense VS3-IR System**

**Submitter's Name, Address, Telephone Number,**

Visionsense Ltd.  
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**Contact Person and Date Prepared**

Raymond Kelly  
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Monroe, CT 06468 USA  
Phone: (203) 880-4091

Date Prepared: August 11, 2015

**Name of Device**

VS3-IR System

**Common or Usual Name / Classification Name**

Endoscopes and Accessories / Infrared Microscope-Endoscope / Angiographic X-ray System

**Predicate Device**

Novadaq Technologies SPY Imaging System (K063345 / K091515)

**Intended Use / Indications for Use**

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.

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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.

## Principles of Operation / Conditions of Use

The VS3-IR System is made up of the following components:

- VS3 3D Endoscope (K123467, K141002, K131434)
- VS3-IR-MMS & ICG Kit (K150018)
- VS3-IR-Endoscope & ICG Kit (not yet assigned).

The following table summarizes FDA clearance history for the VS3-IR system:

Component	FDA Clearance #	Indication
VS3 3D Endoscopes	K123467 (Laparoscope) K141002 (Arthroscope) K131434 (Neurological)	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.
VS3-IR-MMS & ICG Kit	K150018	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.
VS3-IR-Endoscope & ICG Kit	Not yet assigned	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 infra-red imaging during minimally invasive surgery.

This premarket notification adds the IR endoscope to the FDA cleared devices in K123467 (Laparoscope), K141002 (Arthroscope), K131434 (Neurological), and K150018 (MMS), and to change the family brand name to VS3-IR system.

The VS3-IR system includes:

- HD3D camera (cleared K123467, K141002, and K131434)
- Laser Light Source (cleared K123467, K141002, K131434, and K150018)
- CCU (cleared K123467, K141002, K131434, and K150018)
- Display monitor (cleared K123467, K141002, K131434, and K150018)
- MMS-IR (cleared K150018)
- VS3-IR Endoscope (subject of this premarket notification)
- 3rd party Xenon light source (cleared K123467, K141002, K131434, and K150018)
- 3rd party endoscopic light cable (cleared K123467, K141002, K131434, and K150018)
- Light Integrator for white (Xenon) light and IR light from the LLS (cleared K150018)
- ICG Kit (cleared K150018)

The VS3 3D endoscopes (cleared in K123467, K131434, and K141002) are based on the proximal camera concept with a stereoscopic camera block on the proximal side of the endoscope (the handle). The stereoscopic images are transmitted from the visual field at the distal tip of the endoscope to the proximal camera block through an optical transmission system to PC workstations or external display monitors for enhanced viewing or capturing. VS3 includes reusable endoscopes which are cleaned and sterilized using the same methods and are indicated for the same lifecycle.

In addition to traditional endoscopic procedures, VS3-IR system includes support for Infrared (IR) Fluorescence visualization (hereafter referred to as Iridium). Iridium utilizes the VS3 system with scopes that support IR fluorescence visualization. VS3 Iridium Miniature Microscope (VS3-IR-MMS) which was cleared in K150018 is positioned 20cm to 45cm above the patient during an open procedure. The proposed Iridium Endoscopes (VS3-IR-Endoscope) is used during laparoscopic minimally invasive procedures. VS3 Iridium MMS and Endoscopes are designed to work with an approved IR fluorescence dye (Indocyanine Green or ICG), which has excitation at 805nm and emission band between 825nm and 850nm. VS3 Iridium (VS3-IR) provides excitation light to the surgical field to excite the dye molecules and captures emission from the dye using an IR camera.

Both the Iridium MMS and Iridium Endoscope utilize the left channel of the VS3 imaging system (camera and image processor) for IR fluorescence imaging and the right channel for visible light imaging. This structure allows fluorescence imaging to use the same acquisition and processing pathways as the approved 3D endoscopes (cleared in K123467, K131434, and K141002).

## Technological Characteristics

Requirements for the Iridium Endoscope assume that the Iridium Scope is used with the Iridium Camera, CCU, and Laser Light source. Stand-alone functionality of the Iridium Scope is not supported.

#	Feature/Parameter	Value/Description
1	Able to function with no camera	No
2	Working distance	2cm – 7cm from tissue
3	Direction Of View	0°, 30°

## Performance Data

The subject device conforms to the following recognized standards:

Standards No.	Standards Organization	Standards Title
60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (Edition 3).
60601-1	IEC	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
60601-1-4	IEC	Medical electrical equipment - Part 1: General requirements for safety, Collateral standard: Programmable electrical medical systems.
60601-1-4	IEC	Safety of laser products - Part 1: equipment classification, and requirements.

The system software was validated and performs as intended per the pre-specified requirements.

In addition, bench testing was conducted to verify that the subject device can detect and visualize anatomy and blood flow per the proposed indications for use of the Iridium Module.

The Visionsense VS3 system with ICG fluorescence endoscope (VS3 Iridium Endoscope) was bench tested in fluorescence mode so that the endoscope light sources provided both IR (laser light source) and Visible (xenon light source) light to illuminate the simulated surgical field. The left channel of the 3D endoscope was dedicated to visible light imaging, while the right channel of the scope was dedicated to IR imaging during the testing. During testing the laser excitation light triggered IR fluoresce in ICG molecules as intended. The fluorescence light was detected by one of the image sensors in the PHD camera to produce an IR image. The other sensor was used to capture a visible light image of the same scene. The two images were fused together to produce a composite image showing blood flow.

In all instances, the VS3-IR System using the VS3-IR-Endoscope functioned as intended and met all performance acceptance criteria.

## Substantial Equivalence

The VS3-IR-Endoscope as part of the VS3-IR System is substantially equivalent to other legally marketed surgical endoscopes. Specifically, the VS3-IR-Endoscope is substantially equivalent to the cleared Novadaq SPY Imaging device (K091515). As explained in more detail below, the subject VS3-IR-Endoscope has been added to the cleared VS3 base system and VS3-IR-MMS to create the VS3-IR-Endoscope and has the same indications for use and substantially similar technological characteristics and principles of operation as the identified predicate device. A substantial equivalence chart comparing the similarities and differences between the subject and predicate device is provided below

All the components of the subject device and associated software have been cleared in the original VS3 base system 510(k) notices (K123467, K131434, K141002) and the Infrared Iridium VS3-IR-MMS submissions (K150018) including the ICG Kit (K150018) and are included in this submission by reference for purposes of completeness in describing the updated VS3-IR System that the company plans to market.

	<b>VS3-IR IR Endoscope (proposed)</b>	<b>Novadaq Endoscopic SPY (K091515)</b>
Manufacturer	Visionsense Ltd.	Novadaq Technologies Inc
Sterilization	Steam Autoclave	Steam Autoclave
Imaging Agent	IR fluorescence dye (i.e. Indocyanine Green-ICG)	IR fluorescence dye (i.e. Indocyanine Green-ICG)
Imaging Head	Silicon Image Sensor in the camera	Silicon Image Sensor in the camera
Light Source	Infrared Laser	Infrared Laser
Excitation Wavelength	805nm	805nm
Scope Diameter	5.5mm	10mm
Angles of View	0°, 30°	0°, 30°
Imaging	Fluorescent and White Light Imaging	Fluorescent and White Light Imaging
Emission Band	825nm to 850nm	825nm to 850nm
Emission Capture	IR camera	IR camera
Display both Visible and IR images	Yes	Yes

## Conclusions

The VS3-IR System is substantially equivalent to the predicate device. Performance testing demonstrates that the newly added components to the VS3-IR-System performs substantially equivalent to the predicate device, and any differences in technological characteristics do not raise different questions of safety or efficacy compared to the predicate device.