K123467

510(k) Summary

APR 17 2013

Date Prepared: December 11, 2012

Submitter

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Device Information

Trade name: VS3
Common name: Laparoscope, General and Plastic Surgery
Classification Name: Endoscope & Accessories
Review Panel: General and Plastic Surgery
Product Code: GCJ
Device Class: Class II
Regulation: 21 CFR 876.1500.

Predicate Device Information

The predicate device is the VS$_{II}$ (K073279) manufactured by Visionsense Ltd.

Device Description

Intended Use/Indications for Use

The VS3 is intended for viewing internal surgical sites during general endoscopic and laparoscopic surgical procedures.

Technological Characteristics

The VS3 consists of the following components:

- Endoscope
- Light source
- Camera Control Unit (CCU)
- Camera
- Display monitors
- 2D Endoscope coupler

The VS3 Stereoscopic High Definition ("3DHD") system is based on the proximal HD camera concept with a stereoscopic camera block located on the proximal side of the endoscope (the handle). This allows high resolution capture of the 3D video stream. The stereoscopic images are transmitted from the visual field at the distal tip of the endoscope to the proximal camera block containing the HD sensor module. The VS3 system allows for separation of the camera module with image sensor module and electronics from the endoscope shaft housing optical relay components and light fibers. The VS3 system also includes 2D coupler capability that allows the VS3 system to be used with FDA-cleared, third party 2D scopes at user sites to display monocular video.

Principles of Operation

During surgical procedures, the surgeon inserts the endoscope into the surgical site, which is illuminated using the internal or external illumination source. The optical array then functions by capturing both right and left images of the surgical site from different angles. Both images are detected by the camera and transmitted to the CCU. Once the images are received by the CCU, the VS3 generates a stereoscopic signal of both the right and left images that can be sent to the display monitor.

Substantial Equivalence

The Visionsense VS3 Stereoscopic Vision System is substantially equivalent to the Visionsense VS_{II} Stereoscopic Vision System (K073279). Both the proposed VS3 system and the predicate VS_{II} system are designed for providing stereoscopic 3 dimensional (3D) viewing. Both are rigid stainless steel endoscopes with illumination indicated for 3D viewing and illumination of interior surgical sites during general surgical procedures. Both the proposed VS3 and the predicate VS_{II} systems utilize the same basic endoscopy and illumination principles for viewing internal locations and transmission of video to PC workstations or external display monitors for enhanced viewing or capturing. The VS3 has been developed in order to provide clinicians with High Definition (HD) viewing capabilities. The proposed device has the same intended use/indication for use as the predicate device. The addition of HD viewing capabilities in the VS3 is not intended to change the indications or intended use of the subject device.

The proposed VS3 system, like the FDA-cleared VS_{II} system, consists of an endoscopic insertion tube with optics and/or a camera component that detects and transmits images of the surgical site to image processing and viewing components, such as CCU, video displays, or display monitors. The principal difference between the VS3 and the VS_{II} consists of high definition viewing, the location of the camera mounting block being proximal on the proposed device versus distal on the predicate device, and the ability to separate the VS3 endoscope from the VS3 camera. Both devices provide rigid endoscopic insertion tubes that are inserted into the patient's body through surgically prepared access sites. An illumination source that is connected to the endoscope provides light to the surgical site. Optical units and camera systems are employed to capture images of the surgical site and transmit the images to image processing or display units. Both devices are reusable medical

devices which are sterilized using the same methods.

	VS3	VS_{II} (073279)
Indications for Use	Same	Same
Operating Principle	Same	Same
Basic Design	Same	Same
Materials of Construction	Same	Same
Sterilization Method	Same	Same
Visualization Capabilities	3D, HD	3D
Manufacturing Processes	Same	Same

Performance

No performance standards or special controls have been developed under Section 514 of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") for endoscopes. However, the VS3 system and its components follow FDA recognized consensus standards for electrical safety, electromagnetic compatibility, and biocompatibility. In addition, cleaning validation, sterilization validation, and software validation were performed for the subject device. The completed testing listed above demonstrates that the subject device is as safe and effective as the predicate device.

Applicable Standards

- IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (1998); Amendment 1, 1991-11, Amendment 2, 1995.
- IEC 60601-1-1, Medical electrical equipment - Part 1-1: General requirements for safety. Collateral standard: Safety requirements for medical electrical systems (2000).
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility requirements and tests. (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004).
- IEC 60601-2-18, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment (1996). Amendment 1, 2000.
- ISO 14971, Medical devices - Application of risk management to medical devices (2007).
- ISO 8600, Optics and optical instruments -- Medical endoscopes and endoscopic accessories. Part 1:2005; Part 3:1997; Part 4:1997; Part 5:2005; Part 6:2005.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 17, 2013

Visionsense Ltd.
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Gerard J. Prud'homme
Columbia Square
555 Thirteenth Street, Northwest
Washington, District of Columbia

Re: K123467
Trade/Device Name: VS3
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: March 27, 2013
Received: March 27, 2013

Dear Mr. Prud'homme:

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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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, FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K123467

Device Name: **Visionsense VS3 Stereoscopic Vision System**

Indications for Use:

Intended for viewing internal surgical sites during general endoscopic and laparoscopic surgical procedures.

Prescription Use __X__ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S For

(Division Sign-Off)

Division of Surgical Devices

510(k) Number K123467