K131434

510(k) Summary

Date Prepared: June 17, 2013

Submitter

JUL 16 2013

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Device Information

Trade name: VS3 Stereoscopic High Definition Vision System, Model VS3-NE
Common name: Endoscope
Classification Name: Endoscope, Neurological
Review Panel: Neurology
Product Code: GWG
Device Class: Class II
Regulation: 21 C.F.R. §882.1480

Predicate Device Information

Visionsense Ltd VS_{II} (K081102)
Visionsense Ltd VS3 (K123467)

Intended Use/Indications for Use

The VS3 Stereoscopic High Definition Vision System, Model VS3-NE is intended for viewing internal surgical sites during general surgical procedures and for use in visualization of ventricles and structures within the brain during neurological surgical procedures.

Technological Characteristics

The VS3 Stereoscopic High Definition Vision System, Model VS3-NE consists of the following components:

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

The VS3 Stereoscopic High Definition ("3DHD") Vision System, Model VS3-NE 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 Stereoscopic High Definition Vision System, Model VS3-NE 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 Stereoscopic High Definition Vision System, Model VS3-NE also includes 2D coupler capability that allows the VS3 Stereoscopic High Definition Vision System, Model VS3-NE 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 Stereoscopic High Definition Vision System, Model VS3-NE generates a stereoscopic signal of both the right and left images that can be sent to the display monitor.

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 Stereoscopic High Definition Vision System, Model VS3-NE and its components follow FDA recognized consensus standards for electrical safety, electromagnetic compatibility, and biocompatibility:

1. IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (1998); Amendment 1, 1991-11, Amendment 2, 1995.
2. IEC 60601-1-1, Medical electrical equipment - Part 1-1: General requirements for safety. Collateral standard: Safety requirements for medical electrical systems (2000).
3. 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).
4. 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.
5. ISO 14971, Medical devices - Application of risk management to medical devices (2007).
6. 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.

Substantial Equivalence

The Visionsense VS3 Stereoscopic High Definition Vision System, Model VS3-NE has the same intended use and similar indications, principles of operation, and technological characteristics as the cleared VS_{II} (K081102) and VS3 (K123467). Thus, the VS3 Stereoscopic High Definition Vision System, Model VS3-NE is substantially equivalent to its predicate devices.

The following table shows the similarities between the VS3-NE and predicate devices.

	VS3-NE (subject device)	VS_{II} System (K081102) (primary predicate)	VS3 for General Surgery (K123467) (secondary predicate)
Manufacturer	Visionsense Ltd.	Visionsense Ltd.	Visionsense Ltd.
Classification	Endoscope, Neurological 21 C.F.R. §882.1480 Product code GWG	Endoscope, Neurological 21 C.F.R. §882.1480 Product code GWG	Laparoscope, General & Plastic Surgery 21 C.F.R. §876.1500 Product code GCJ
Indications for Use	Intended for viewing internal surgical sites during general surgical procedures and for use in visualization of ventricles and structures within the brain during neurological surgical procedures	Intended for viewing internal surgical sites during general surgical procedures and for use in visualization of ventricles and structures within the brain during neurological surgical procedures	Intended for viewing internal surgical sites during general endoscopic and laparoscopic surgical procedures
Endoscope type	Rigid Stainless Steel	Rigid Stainless Steel	Rigid Stainless Steel
Endoscope diameter	4 - 5.5 mm	4 - 5 mm	4 - 5.5 mm
Endoscope length	175 - 300 mm (±5 mm)	175 - 300 mm (±5 mm)	175 - 300 mm (±5 mm)
Field of view	70°-95°	70°	70°-95°
Direction of view	0° - 70°	0° - 70°	0° - 70°

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 16, 2013

Visionsense Ltd
c/o Mr. Gerard J. Prud'homme
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

Re: K131434

Trade/Device Name: VS3 Stereoscopic High Definition Vision System, Model VS3-NE

Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: June 17, 2013
Received: June 17, 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 contact 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. 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,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131434

Device Name: Visionsense VS3 Stereoscopic High Definition Vision System, Model VS3-NE

Indications For Use:

Intended for viewing internal surgical sites during general surgical procedures and for use in visualization of ventricles and structures within the brain during neurological surgical procedures.

Prescription Use __x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.07.15 18:35:33 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number ___K131434_____