



Food and Drug Administration
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February 22, 2016

Visionsense Ltd
% Raymond Kelly
Licensale Inc
57 Lazy Brook Rd
Monroe, Connecticut 06468

Re: K153548

Trade/Device Name: VS3 Stereoscopic High Definition Vision System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, GWG
Dated: December 25, 2015
Received: January 8, 2016

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); 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" (21 CFR 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,

David Krause -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)

K153548

Device Name

VS3-ETV

Indications for Use (Describe)

The system is intended for viewing internal surgical sites during general surgical procedures, 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 large joint arthroscopic procedures.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary Visionsense VS3-ETV

Submitter's Name, Address, Telephone Number,
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Contact Person and Date Prepared

Raymond Kelly
57 Lazy Brook Rd
Monroe, CT 06468 USA
Phone: (203) 880-4091

Date Prepared: October 25, 2015

Name of Device

VS3-ETV

Common or Usual Name / Classification Name

Neurological Endoscope / Arthroscope

Product Code / Regulation Number

GWG / HRX 882.1480 / 888.1100

Review Panel

Neurology / Orthopedic

Device Class: Class II

Predicate Device

VS3 Stereoscopic High Definition Vision System, Model VS3 (K141002)

Intended Use / Indications for Use

The system is intended for viewing internal surgical sites during general surgical procedures, 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 large joint arthroscopic procedures.

Principles of Operation / Conditions of Use

The VS3 ETV endoscope is the same endoscope as the predicate VS3 with the addition of 3 working channels. The endoscope is designed and manufactured the same way. The endoscope is a rigid metal shaft that uses a proximal sensor module which is mounted onto a camera block on the proximal side of the endoscope (the handle). The endoscope uses stereoscopic images which are transmitted from the visual field at the distal end of the scope through an optical transmission (for left and right channels). The endoscope camera sensor module picks up the left and right images of the scene inside the body and delivers them to the external display. The endoscope incorporates fiber optic threads that transfer the light from the illumination unit to the surgical scene. The VS3 ETV endoscope contains 3 working channels. The endoscope utilizes the same principle of operation, software, system architecture, camera and visual viewing technologies, illumination sources, display monitors, carts, CCU and couplers as the predicate VS3.

Technological Characteristics / 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.

Performance testing consisting of reuse validation, cleaning and disinfection validation, autoclave and sterilization validation were performed to demonstrate the additional working channels do not present changes in reuse handling and processing compared to the predicate device. No new biocompatibility assessments or electrical safety or EMC testing was required as the only modification to the VS3 system was the addition of 3 working channels.

Substantial Equivalence

Feature/Parameter	Proposed VS3-ETV	Predicate VS3 (K141002)
Able to function with no camera	No	No
Working distance range	8mm - 70mm	8mm - 70mm
Field Of View	70° - 95°	70° - 95°
Direction of view	0° - 70°	0° - 70°
Horizontal resolution	>199 lpf	>199 lpf
Vertical resolution	>199 lpf	>199 lpf
Identification	Support functionality to permit the system to identify scope	Support functionality to permit the system to identify scope
Irrigation Sheath	Support an optional irrigation sheath with a standard Storz-style connector	Support an optional irrigation sheath with a standard Storz-style connector
Endoscope diameter	4 - 5.5 mm	4 - 5.5 mm
Endoscope length	175 - 300 mm (±5 mm)	175 - 300 mm (±5 mm)
Depth of field	7 - 30mm and 15 - 60mm	7 - 30mm and 15 - 60mm
Working Channels	yes	no

Working/Irrigation Channels Reference Device

K983365 (Aesculap Minop System) cleared December 1998 is used as reference device to show precedence of the irrigation and working channels.

Conclusions

The VS3-ETV is substantially equivalent to the predicate device. Performance testing demonstrates that the modified device 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.