510(k) Summary K141002

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: April 11, 2014

Applicant
Visionsense Ltd
20 Hamagshimim Street
Petach Tikva 49348
Israel

Contact Person
Raymond Kelly
Licensale Inc.
57 Lazy Brook Rd
Monroe, CT 06468 USA
Phone: (203) 880-4091

Alternate Contact
Azi Ben-Yishai
20 Hamagshimim Street
Petach, Tikva 49348 Israel
Phone: +972 (3) 9244339
Facsimile: +972 (3) 9244335

Device Information
Trade name: VS3 Stereoscopic High Definition Vision System, Model VS3-OT
Common name: Endoscope, Arthroscope
Classification Name: Arthroscope
Review Panel: General and Plastic Surgery
Product Code: HRX
Device Class: Class II
Regulation: 21 C.F.R. §888.1100

Predicate Device Information
Visionsense Ltd VS3 for Neurosurgery (K131434)
Visionsense Ltd VSii Arthroscope (K082355)
Karl Storz C-Mount Arthroscope (K983142)

Intended Use/Indications for Use
The VS3-OT 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 knee arthroscopic procedures.

Technological Characteristics
The VS3 Stereoscopic High Definition Vision System, Model VS3-OT 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-OT 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-OT 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-OT also includes 2D coupler capability that allows the VS3 Stereoscopic High Definition Vision System, Model VS3-OT 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-OT 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-OT and its components follow FDA recognized consensus standards for electrical safety, electromagnetic compatibility, and biocompatibility:

- AAMI/ANSI ES60601-1:2005:A1:2012 Medical electrical equipment - part 1: general requirements for basic safety and essential performance.
- AAMI/ANSI/IEC 60601-1-2:2007 Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.

- IEC 60601-2-18:2009 Medical electrical equipment - part 2-18: particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 14971:2007 Medical devices - application of risk management to medical devices.
- AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process.

Substantial Equivalence

The Visionsense VS3 Stereoscopic High Definition Vision System, Model VS3-OT has the same intended use and similar indications, principles of operation, and technological characteristics as the cleared VS3 for Neurosurgery (K131434), VSii Arthroscope (K082355), and Karl Storz Arthroscope (K983142). Thus, the VS3 Stereoscopic High Definition Vision System, Model VS3-OT is substantially equivalent to its predicate devices.

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

	VS3-OT (subject device)	VS3 Neurosurgery (K131434)	VSii Arthroscope (K082355)	Karl Storz C-Mount Arthroscope (K983142)
Manufacturer	Visionsense Ltd.	Visionsense Ltd.	Visionsense Ltd.	Karl Storz
Classification	Arthroscope 21 C.F.R. §888.1100 Product code HRX	Endoscope, Neurological 21 C.F.R. §882.1480 Product code GWG	Arthroscope 21 C.F.R. §888.1100 Product code HRX	Arthroscope 21 C.F.R. §888.1100 Product code HRX
Indications for Use	Intended for viewing internal surgical sites during surgical procedures	Intended for viewing internal surgical sites during surgical procedures	Intended for viewing internal surgical sites during surgical procedures	Intended for viewing internal surgical sites during surgical procedures
Endoscope type	Rigid Stainless Steel	Rigid Stainless Steel	Rigid Stainless Steel	Rigid Stainless Steel
Endoscope diameter	4 – 5.5mm	4 - 5.5 mm	4 - 5 mm	4mm
Endoscope length	175 - 300 mm (±5 mm)	175 - 300 mm (±5 mm)	175 - 300 mm (±5 mm)	175mm
Working distance range	7 - 70mm	7 - 70mm	7 - 60mm	7 - 70mm
Field of view	70°-95°	70°-95°	70°	95°
Direction of View	0° - 70°	0° - 70°	0° - 70°	0° - 70°
Horizontal Resolution	>199 lpf	>199 lpf	>150 lpf	>199 lpf
Vertical Resolution	>199 lpf	>199 lpf	>140 lpf	>199 lpf
Depth of Field	7 - 30mm and 15 - 60mm	7 - 30mm and 15 - 60mm	7 - 30mm and 15 - 60mm	7 - 30mm and 15 - 60mm

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

June 26, 2014

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

Re: K141002
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: April 7, 2014
Received: April 18, 2014

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141002

Device Name

VS3 Stereoscopic High Definition Vision System, Model VS3-OT

Indications for Use *(Describe)*

The VS3-OT 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 knee 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)*

Joshua C. Nipper -S

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."