K073279

Visionsense Ltd.'s VS_{II} System 510(k) Summary

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Name of Device	VS_{II} – Visionsense Stereoscopic Vision System
Common or Usual Name	Laparoscope system
Classification Names	Laparoscopes and accessories (21 C.F.R. § 876.1500)
Product Codes	GCJ
Submitter	Visionsense Ltd. 20 Hamagshimim Street P.O. Box 7149 Petach Tikva 49348 Israel Phone: 011-972-3-924-4339 Facsimile: 011-972-3-924-4335
Contact Person:	Gerard J. Prud'homme Hogan & Hartson LLP 555 13TH Street, NW Washington, DC 20004 Phone: (202) 637-5735 Facsimile: (202) 637-5910
Date Prepared:	November 20, 2007

Predicate Devices

ELRAN 01 Stereoscopic Laparoscope (K002431), Visionsense Ltd. (previously known as Envision Advanced Medical Systems Ltd.)

Intended Use

The VS_{II} System is intended for viewing internal surgical sites during general endoscopic and laparoscopic surgical procedures.

Substantial Equivalence

The VS_{II} System is a modification to the ELRAN 01 Stereoscopic Laparoscope (K002431). The VS_{II} System has the same intended use and similar indications, principles of operation, and technological characteristics as the ELRAN 01 Stereoscopic Laparoscope. The minor differences in the modified device's technological characteristics do not raise any new questions of safety or effectiveness. Performance data demonstrates that the VS_{II} System is as safe and effective as the ELRAN 01 Stereoscopic Laparoscope. Thus, the VS_{II} System is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Visionsense, Ltd.
% Hogan & Hartson, LLP
Mr. Gerard J. Prud'homme
Columbia Square
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

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Re: K073279
Trade/Device Name: VS_{II} – Visionsense Stereoscopic Vision System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: February 29, 2008
Received: February 29, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073279

Device Name: VS_{II} – Visionsense Stereoscopic Vision System

Indications For Use: The VS_{II} system is intended for viewing internal surgical sites during general endoscopic and laparoscopic surgical procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K073279