K082667

OCT 30 2008

# SECTION 5: 510(k) Summary

visionSENSE

**Submitter**

Visionsense Ltd.
(Previously known as
Envision Advanced Medical Systems)
20 Hamagshimim Street
P.O. Box 7149
Petach Tikva 49348
Israel
Owner/Operator Number: 9042467
Establishment Registration Number: 9616637

**Contact Person(s)**

Gerard J. Prud'homme
Partner
Hogan & Hartson LLP
555 13th Street, NW
Washington, DC 20004-1108
Tel: (202) 637-5735
Fax: (202) 637-5910
E-mail: GJPrudhomme@hhlaw.com

**Date Prepared**

September 12, 2008

**Device Information**

**Trade name:** $VS_{II}$
**Common name:** Visionsense Stereoscopic Vision System
**Classification Name:** Nasopharyngoscope
**Review Panel:** Ear, Nose and Throat
**Product Code:** EOB
**Device Class:** Class II

**Predicate Devices**

| 510(k) number | Trade or propriety name | Manufacturer |
|---|---|---|
| K081102, K073279 | $VS_{II}$ - Visionsense Stereoscopic Vision System | Visionsense Ltd. |
| K032822 | asap ENT Endoscope | asap Endoscopic Products GmbH |

K082669

**Intended Use/Indications for Use**
The $VS_{II}$ is intended to visualize the nasal cavity and nasal pharynx during diagnostic and therapeutic procedures, as well as 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/Principles of Operation**
Visionsense Stereoscopic Vision System ($VS_{II}$) consists of a proprietary CCD camera, embedded in the distal end of a rigid metal endoscope. An array of miniature lenses – the Lenticular Array (LA) - built onto the CCD surface during the wafer fabrication process, captures the image from slightly different angles, thus mimicking the natural human "stereo vision" obtained when the eyes simultaneously pick up two different images of the same object (right and left). The captured image is subsequently transmitted to a PC workstation, processed and presented on a stereoscopic display panel. Images are recorded and may be later downloaded for further analysis.

**Substantial Equivalence**
Visionsense's $VS_{II}$ was previously cleared by FDA 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 (K081102, K073279). The subject device is technologically similar to the device for which FDA has granted marketing clearance, except – Visionsense is now seeking to expand the indication to include visualization of the nasal cavity and nasal pharynx during diagnostic and therapeutic procedures.

Visionsense's $VS_{II}$ System is also substantially equivalent to other previously cleared nasopharyngoscopes/ endoscopes, namely the asap ENT Endoscope (K032822). Performance data, to support this claim, is included in the body of the submission file. Thus, the $VS_{II}$ System is substantially equivalent to the identified predicate devices.

**Performance**
No performance standards or special controls have been developed under Section 514 of the Federal Food, Drug, and Cosmetic Act ("FDC Act") for nasopharyngoscopes. However, the $VS_{II}$ System and its components comply with international standards for electrical safety, electromagnetic compatibility, and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Visionsense, Ltd.
c/o Gerald J. Prud'homme
Hogan & Hartson, LLP
555 13th Street, NW
Washington, DC 20004-1108

OCT 30 2008

Re: K082667
Trade/Device Name: $VS_{II}$ Visionsense Stereoscopic Vision System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: II
Product Code: EOB
Dated: September 12, 2008
Received: September 12, 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,

Malvina B. Eydelman, M.D.

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number:

Device Name:

$VS_{II}$ – Visionsense Stereoscopic Vision System

Indications for Use:

The $VS_{II}$ is intended to visualize the nasal cavity and nasal pharynx during diagnostic and therapeutic procedures, as well as 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 ___✓___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K082667