we sense
Pioneers in Brain Sensing Technology

We Sense Ltd.
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K082404

510(k) Summary

FEB 25 2009

As Required by 21 CFR 807.87(k)510 (k) Summary

1. Subscribers Name & Address

WE SENSE LTD
2,Eksal Street ,
Nazareth 16000,
Israel
Tel: (972) 4 656-4222
Fax: (972) 4 656-4282
Official Correspondent: Mr. Nabil Jadaon

2. Trade Name Navigation Probes

3.Predicate Device Identification

Common Name	Product Code	Class	Regulation Number
Depth electrode	84 GZL	II	21 CFR 882.1330

4. Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	510(k) #
FHC microTargeting Electrodes	K033173

6. Device Description

NavigationProbes are equipped with a Micro tip and a Macro tip.
The micro tip is used to for recording cell potentials of single cells or of cell clusters and for MicroStimulation.
The Macro tip is used for stimulation and recording of local field potentials.

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7. Intended Use:

The Navigation probes are intended to be used in the human brain for the recording of Neuro potentials of single brain cells and for electrical stimulation of small areas in the brain.

8. Summary of technological characteristics of Device and Predicate Device:

The functionality for the Navigation Probes are equivalent to its predicate device the FHC Inc, microTargeting Electrode (K033173) in safety and effectiveness. The fundamental technical characteristics are similar to those of the predicate device and are listed on the comparison charts provided in this 510 k submission.

Nabil Jadaon
General Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2009

We Sense Ltd.
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Nazareth
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Re: K082404
Trade/Device Name: Navigation Probes
Regulation Number: 21 CFR 882.1330
Regulation Name: Depth electrode
Regulatory Class: II
Product Code: GZL
Dated: January 21, 2009
Received: February 2, 2009

Dear Mr. Jadaon:

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.

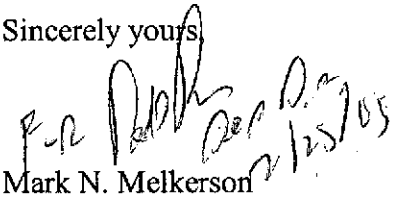
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or 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

Indication for Use

510(k) Number K 082404

Device Name: Navigation Probes

Indication For Use:

We Sense Navigation Probes electrodes are intended to be used in operation room during neurosurgery for temporary (less than two hours) recording and stimulation of defined small area in the brain, and for recording electrical signals from target brain cells. These electrodes can be used only by professional staff and not sell over the counter

Prescription Use only (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K082404