JUN 2 9 2005

K051448

510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	MedicSense, Ltd. Galdani Bldg 58b Amal St. Kiriat Arie, Petach Tikya, Israel 47103 www.medicsense.com
1. (b)	***Manufacturer Address:***	Medoc, Ltd., Advanced Medical Systems Ha' oren St. 45 Ramat Yishai, Israel 30095
	Mfg. Phone:	972-4-9830751
	Contact Person:	Udi Gafni, President
	Date:	May 31, 2005
2.	***Device & Classification Name:***	Evoked response thermal stimulator, Class 2, Product Code NTU, 21 CFR 882.1870- Modified Contact Heat-Evoked Potential Stimulator (CHEPS)
3.	***Predicate Device:***	Contact Heat-Evoked Potential Stimulator K041908
4.	***Description:***	The Modified Contact Heat-Evoked Potential Stimulator (CHEPS) is an advanced, computerized thermal stimulator designed for advanced pain research. This non-invasive device can be used as a stimulator for creating sensation and pain stimuli, in the sensory nerves fibers.
5.	***Intended Use:***	The Modified Contact Heat-Evoked Potential Stimulator (CHEPS) is indicated for the use in evaluating the functionality of human pain reception and transmission of sensory pathways
6.	***Comparison of Technological Characteristics:***	With respect to technology, the Modified Contact Heat-Evoked Potential Stimulator (CHEPS) is substantially equivalent to its predicate device which is the Original Contact Heat-Evoked Potential Stimulator (CHEPS). The primary differences between the devices are the enclosure, the addition of a thermode, the Ramp & Hold option, and optional languages.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

Medoc, Ltd. Advanced Medical Systems
C/o Mr. George J. Hattub, RAC & CQE
Medicsense
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K051448
Trade/Device Name: Modified Contact Heat-Evoked Potential Stimulator (CHEPS)
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: II
Product Code: NTU
Dated: May 31, 2005
Received: June 3, 2005

Dear Mr. Hattub:

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 Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting 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): K 051448

Device Name: Modified Contact Heat-Evoked Potential Stimulator (CHEPS)

Indications For Use: The Modified Contact Heat-Evoked Potential (CHEPS) is indicated for the use in evaluating the functionality of human pain reception and transmission of sensory pathways.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _ (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)

Division Sign-Off
Division of General, Restorative and Neurological Devices
510(k) Number K051448