DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2006

Medoc, Ltd., Advanced Medical Systems
c/o Mr. George J. Hattub
Senior Staff Consultant
MedicSense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K052357
Trade/Device Name: Pathway - ATS/CHEPS
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: II
Product Code: NTU
Dated: December 20, 2005
Received: December 22, 2005

Dear Mr. Hattub:

This letter corrects our substantially equivalent letter of January 19, 2006.

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 (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 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 continue 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" (21 CFR 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/dsma/dsmamain.html

Sincerely yours,

Barbara Bucher MD

Mark N. Melkerson
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):

Device Name: PATHWAY- ATS/CHEPS

Indications For Use: The PATHWAY- ATS/CHEPS is indicated for the use in evaluating the functionality of human pain reception and transmission of sensory pathways.

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)

Barbara Brehm for MKM

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K052357

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JAN 19 2006

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:	August 26, 2005
2.	***Device & Classification Name:***	Evoked response thermal stimulator, Class 2, Product Code NTU, 21 CFR 882.1870- Trade-name of device: PATHWAY- ATS/CHEPS
3.	***Predicate Device:***	Modified Contact Heat-Evoked Potential Stimulator K051448
4.	***Description:***	The PATHWAY- ATS/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 PATHWAY- ATS/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 PATHWAY- ATS/CHEPS is substantially equivalent to its predicate device which is the Modified Contact Heat-Evoked Potential Stimulator (CHEPS). The primary differences between the devices is the ability of one of its thermodes to provide lower temperatures.