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SUMMARY AND CERTIFICATION

FEB 2 5 2005

A. 510(k) Summary

Submitter: Medoc Ltd. Advanced Medical Systems

Contact Person:
Alquest, Inc
Tracy Gray RN, BS, RAC
Sr. Consultant and Consultant to Medoc
4050 Olson Memorial Hwy Suite 350
Minneapolis, MN 55422.

Date Prepared: February 2, 2005

Trade Name: Contact Heat-Evoked Potential Stimulator (CHEPS)

Classification, Name and Number:
Class II
No assigned classification number, as with the predicate devices
21 CFR 882

Product Code: LQW/LLN

Predicate Device(s): The subject device is substantially equivalent to the following device(s):

- GSA Genito Sensory Analyzer (K010981), manufactured by Medoc Ltd. Advanced Medical Systems.
- TSA-2001 Thermal Sensory Analyzer (K922052), manufactured by Medoc Ltd. Advanced Medical Systems.

Device Description: The Contact Heat-Evoked Potential Stimulator (CHEPS) is a computerized thermal stimulator that produces a heating stimulation in rate of 70°C/sec, enabling delivery of painful stimuli from a baseline to 55°C in 250 milliseconds. The system consists of the CHEPS control unit, external cooling unit, 27mm diameter thermode probe, thermode cables, and software. The software program requires the use of an IBM compatible notebook or desktop computer, which is not supplied. Also, the following are optional components: MRI-safe thermode and cables and cart.

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Intended Use:	The Contact Heat-Evoked Potential Stimulator (CHEPS) is indicated for the use in evaluating the functionality of human pain reception and transmission of sensory pathways.
Functional and Safety Testing:	The device underwent mechanical, physical, and biocompatibility testing as described in **Section 6** and **Section 7** of this submission. The results of testing were successful. The device performed as designed and met, or exceed, all product specifications.
Conclusion:	Medoc Ltd. Advanced Medical Systems considers the Contact Heat-Evoked Potential Stimulator (CHEPS) equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in function, design, materials, and indication for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 5 2005

Medoc Ltd. Advanced Medical Systems
c/o Ms. Tracy Gray, RN, BS, RAC
Alquest, Inc.
4050 Olson Memorial Highway, Suite 350
Minneapolis, Minnesota 55422

Re: K041908
Trade/Device Name: 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: January 17, 2005
Received: January 21, 2005

Dear Ms. Gray:

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,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
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): Pending

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

Indications For Use:

The Contact Heat-Evoked Potential Stimulator (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 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

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

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