JAN 2 3 2004

7.0 PREMARKET NOTIFICATION 510(K) SUMMARY

Sponsor:	friendly sensors AG August-Bebel-Str. 10 07743 Jena GERMANY Telephone: +49 3641-637343 Fax: +49-3641-6373-11 Contact: Dr. Werner Schwarze
Manufacturer:	OLPE Jena GmbH Friedrich-Hund-Straße 3 07745 Jena GERMANY Telephone: +49 (36 41) 65 30 85 Facsimile: +49 (36 41) 65 36 76 Contact: Mr. Nissel
Registration:	To be assigned
Contact Person:	Trish Landry M Squared Associates, Inc. 719 A Street, NE Washington DC 20002 Telephone: 202-546-1262 Fax: 202-546-3848 E-mail: tlandry@msquaredassociates.com
Trade Name of Device:	sonoSens®
Common Name:	Range of Motion Measurement Device
Classification name:	Goniometer with Electrodes
Product Code:	NKI
Regulation Class:	Class II
Regulation Number:	§888.1500

Device Description: The sonoSens® is a non-invasive device indicated for use in real-time measurement of range of motion. The measuring device consists of a monitor central processing unit (CPU), the power supply, and an infrared interface for data transfer. The device is connected to eight sensors via cables. Each sensor is directly attached to the skin with an adhesive pad.

Indications for Use: Continuous real-time measurement of range of motion.

Basis for Substantial Equivalence

sonoSens® (proposed device): The friendly sensors sonoSens® requires that eight small sensors be attached to the area of the body being measured using disposable adhesive pads. Low-intensity ultrasound energy is emitted between sensors applied to the skin (the sender sensor sends an ultrasonic signal to the receiver sensor). The amount of time that the ultrasonic signal takes to travel from the sending sensor to the receiving sensor is measured by the sonoSens®. The data recorded by the monitor is transferred to the personal computer via an infrared interface. The data may be viewed immediately or stored on the hard disk of the computer for further analysis. The computer software enables the development of graphical displays of the patient range of motion data. The system has a report generator capability that provides reports, including tables, graphs and text.

3-D Spine (predicate device): The 3-D Spine requires that a small passive receiver/sensor be attached to the forehead, using a neoprene head strap, and a second strap be attached at other spinal locations, using double-sided adhesive tape. The relative motion of the two sensors, as detected by the change in the field strength, and orientation of the magnetic field lines, is compared to the resulting angular changes recorded by the monitor. The relative difference in displacement and orientation between the two sensors describes the precise 3-D motion performed by the patient. Data is received by the monitor and displayed on the computer monitor. The data may be viewed immediately or stored on the hard disk of the computer for further analysis. The computer software enables the development of three-dimensional and graphical displays of the patient range of motion data. The system has a report generator capability that provides a flexible or customized report, including tables, graphs and text.

Dualer IQ™ Inclinometer and Tracker ROM™ Computerized Dual Inclinometry System (predicate device): The Dualer IQ™ Inclinometer and Tracker ROM™ Computerized Dual Inclinometry range of motion measurement system involves the use of two handheld monitors that measure the angles of the patient's range of motion based on gravitational pull. The angle measured shows on a liquid crystal display. The monitors are either held directly on the patient by the practitioner or attached to the patient using straps. The data recorded on the monitors are transferred to a personal computer by plugging the monitors into a central unit, the Tracker ROM™ device. The Tracker ROM™ device functions as an interface between the Dualer IQ™ Inclinometer monitors and the personal computer. The data from the monitors are transferred to a personal computer in which the Tracker ROM™ software is used to provide customized reports of range of motion data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 3 2004

Friendly Sensors AG
C/o Ms. Trish Landry
M Squared Associates, Inc.
719 A Street, NE
Washington, DC 20002

Re: K033193
Trade/Device Name: sonoSens®
Regulation Number: 21 CFR 888.1500
Regulation Name: Goniometer
Regulatory Class: II
Product Code: NKI
Dated: October 1, 2003
Received: October 27, 2003

Dear Ms. Landry:

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 (301) 594-4659. 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/dsma/dsmamain.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): K033193

Device Name: sonoSens®

Indications For Use: Continuous real-time measurement of range of motion.

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)

Miriam C. Provost

Division of General, Restorative
and Neurological Devices

510(k) K033193