K082893

DEC 0 5 2008

ESI Inc.
510(k) Submission
Prager Shell®

510(k) Summary
September 3, 2008

(1) Submitter Information

Name: ESI, Inc.

Address: 2915 Everest Ln N.

Plymouth, MN 55447

Telephone Number: 763-473-2533

Contact Person: Dr. George Myers

Medsys Inc.

377 Rt. 17 S

Hasbrouck Heights, NJ 07604

201-727-1703

Date Prepared: September 3, 2008

(2) Name of Device:

Trade Name: Prager Shell

Common Name: Rigid Water Path for Ultrasonic Transducers

Classification Name: Scleral Shell (Accessory to ultrasound system).

(3) Equivalent legally-marketed devices:

Preamendment device Water Bath for Sonometrics Coleman A-B scan system.

(4) Description

The shell is a cylinder with an open top and open bottom,. The open bottom end is contoured at the rim to conform to the curvature of the eye. The ultrasonic transducer is placed in the Prager

Shell® from above. Once placed on the eye the shell is filled with balanced salt solution (BSS) and the probe distal end is immersed in the BSS. It is not sold sterile and is reusable. Tubing kits are available to connect the shell to the BSS source. These kits are distributed by ESI but not manufactured by it.

(5) Intended Use

The Prager Shell® is a plastic device intended to provide a water path between an ultrasound transducer and the eye. It is intended for A-scan biometry of the eye.

(6) Technological Characteristics

. The Prager Shell is made of a biologically-compatible rigid plastic. Each model fits the transducers of specific ultrasound manufacturers. They are fitted with mechanisms so that they may be locked in place on the transducers

(7) Performance data

(a) Non-clinical tests

Biocompatibility tests have been done.

(b) Clinical tests

Not required

(8) Conclusions

The Prager Shell is equivalent in safety and efficacy to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 5 2008

ESI, Inc.
% Mr. George Myers
President
Medsys, Inc.
377 Route 17 S
HASBROUCK HEIGHTS NJ 07604

Re: K082893
Trade/Device Name: Prager Shell
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: ITX
Dated: September25, 2008
Received: September 30, 2008

Dear Mr. Myers:

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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 Biometrics' (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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082893

Device Name: Prager Shell

Indications For Use:

The Prager Shell® is a plastic device intended to provide a water path between an ultrasound transducer and the eye for A-scan biometry of the eye.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082893