

K063433

MEDA. CO., LTD

510(k) Premarket Notification
Model ODM-2100/2200 Ultrasonic A/B Scanner For Ophthalmology

Attachment 8
510(K) Summary

510(k) SUMMARY

JAN 29 2007

1) Submitter Information

Name: MEDA. Co., Ltd.

Address:

Room D, F3, Building C2, Xinmao Science Skill Park,
Huayuan Industry Development Area, Tianjin, China

Phone: 86-22-83713808

Fax: 86-22-83713880

Contact person: **Edward A. Kroll**

Spectre Solutions, Inc.

5905 Fawn Lane

Cleveland, Ohio 44141

Phone: (440) 546-9810

Fax: (440) 546-9124

Data Prepared: July 10, 2006

2) Name of Device

Trade Name: ODM-2100 Ultrasonic A/B Scanner for Ophthalmology

ODM-2200 Ultrasonic A/B Scanner for Ophthalmology

Common Name: Ultrasonic A and B Scan System for Ophthalmology

Classification Name: Ultrasonic Pulsed Echo Imaging System

Regulation Number: 892.1560

Product Code: 90-IYO

3) Predicate Devices

Sonomed Medical E-Z Scan™ AB5500⁺, K040668

4) Intended Use

The intended use of the ODM-2100 & ODM-2200 includes the location and visualization of ophthalmic disorders and measurement of ocular distances.

5) Device Description

The ODM-2100/2200 combines a B-scanner used for the visualization by ultrasound of the eye and orbit and an A-scan used for intraocular measurements. The intended use of this system includes the localization and visualization of ophthalmic disorders and measurement of the eye and orbit.

The ODM-2200 uses the same software and hardware (Switch power supply, P.C. board, user's interface, transducer etc.) as ODM-2100 does. The only difference is that:

ODM-2100 uses a portable housing and built-in 10-inch video monitor;
ODM-2200 uses standard SVGA. LCD monitor.

6) Technological characteristics

a) Devices Description

The ODM-2100/2200 includes B-mode ultrasonic cross-section imaging and A-mode axial biometric parameter measurement. Users can switch between these two modes through keyboard.

In B-mode, the 10MHz transducer emits ultrasound under electric pulse and then receives and stores its echo reflected by interfaces of different tissues. Through the sector scanning of transducer, several echo lines create real time image of eye tissue and the image is displayed on the monitor.

In A-mode, the 10MHz transducer transmits ultrasound into eye tissue and receives its echo reflected back by anterior chamber, lens and vitreum. Each length and their sum (AL) are calculated by measuring the time spent in different parts.

b) Performance Data

1) Non-clinical test

Compliance Tests for ODM-2100 are as follows:

Safety Test (IEC 60601-1, Tested by TÜV)

EMC Test Report (IEC 60601-1-2, Tested by TÜV)

Acoustic output Test (FDA Guidance Document "*Information for Manufacture Seeking Marketing Clearance of Diagnostic Ultrasound System and Transducers*")

Biological Safety Test (ISO 10993, Tested by TÜV)

2) Clinical test: Not required

3) Conclusions

The ODM-2100/2200 Ultrasonic A/B Scanner for Ophthalmology is equivalent in safety and efficacy to the legally marketed predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Meda. Ltd.
% Mr. Edward A. Kroll
President
Spectre Solutions, Inc.
5905 Fawn Lane
CLEVELAND OH 44141

JAN 29 2007

Re: K063433
Trade Name: Model ODM 2100 and 2200 Ultrasonic A/B Scanner for Ophthalmology
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: November 8, 2006
Received: December 5, 2006

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Model ODM 2100 and 2200 Ultrasonic A/B Scanner for Ophthalmology, as described in your premarket notification:

Transducer Model Number

A-Scan (10MHz)

B-Scan (10MHz)



Protecting and Promoting Public Health

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

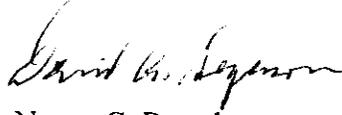
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your 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 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) 276-0120. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (240) 276-3666.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): ~~TBD~~ K063433

Device Name: Model ODM 2100 and 2200 Ultrasonic A/B Scanner for Ophthalmology

Indications for Use:

- Ultrasound Imaging of the eye
- Axial biometric parameter measurement of the eye

Prescription Use X
(Part 21 CFR 801 Subpart D)

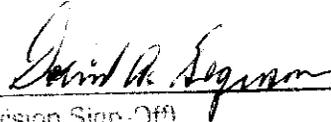
AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Pediatric Devices
Device Number K063433

Attachment 1

K063433

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ODM-2100/2200 Ultrasonic A/B Scanner for Ophthalmology

Transducer: B-Scan (10MHz)

Intended Use: Diagnostic ultrasound imaging

Clinical Application	Mode Of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other* (Specify)
Ophthalmic		N								
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Contents: _____

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

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David B. Segerson
 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and General Devices
 File Number K063433

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

K063433

System: ODM-2100/2200 Ultrasonic A/B Scanner for Ophthalmology

Transducer: A-Scan (10MHz)

Intended Use: Diagnostic ultrasound imaging

Clinical Application	Mode Of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other* (Specify)
Ophthalmic	N									
Fetal										
Abdominal										
Intraoperative (Specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (Specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Contents: _____

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

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

David G. Segman

 (Division Sign-Off)

Division of Reproductive, Abdominal,
 and Radiological Devices

510(k) Number K063433