APR 1 3 2004

K040668

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Sonomed Inc.
Special 510(k)
E-Z Scan AB5500+

510(k) Summary
February 25, 2004

(1) Submitter Information

Name: Sonomed Inc..

Address: 3000 Marcus Avenue
Lake Success, NY 11042

Telephone Number: 516-354-0900

Contact Person: Dr. George Myers
Medsys Inc.
377 Rt. 17 S
Hasbrouck Heights, NJ 07604
201-727-1703

Date Prepared: February 25, 2004

(2) Name of Device:

Trade Name: Sonome E-Z Scan AB5500+
Common Name: Portable ophthalmic A and B scan system
Classification Name: System, Imaging, Ultrasonic, Ophthalmic, 980IYO

(3) Equivalent legally-marketed devices:

1. Sonomed Ophthalmic B-scan B-3000, K844031
2. Sonomed A-scan A-2000, K843696

(4) Description

The E-Z Scan AB5500+ combines a contact 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.

(5) Intended Use

. The intended use of this system includes the localization and visualization of ophthalmic disorders and measurement of ocular distances.

(6) Technological characteristics

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The E-Z Scan AB5500+ is a conventional ophthalmic B-scan system using a motor-driven transducer and angle sensor for scanning and a conventional contact A-scan system. The transducer frequency is 10 MHz. It uses a motor-driven 10 MHz transducer with an attached angle encoder. The display is on a video touch screen, also used for controlling the system. The entire device is computer-controlled by an internal microprocessor. The A-scan uses a separate 10 MHz transducer and its own pulser-receiver.

(b) Performance data

(1) Non-clinical tests

Both ultrasonic emissions tests and accuracy and validation tests have been done.

(2) Clinical tests

Not required

(3) Conclusions

The Sonomed E-Z scan AB5500+ 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

APR 1 3 2004

Mr. Barry Durante
Executive Vice President
SONOMED, Inc.
3000 Marcus Avenue
LAKE SUCCESS NY 11042

Re: K040668
Trade Name: Sonomed E-Z Scan AB 5500+
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: Class II
Product Code: 90 IYO and ITX
Dated: March 1, 2004
Received: March 17, 2004

Dear Mr. Durante:

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 Sonomed E-Z Scan AB 5500+, as described in your premarket notification:

Transducer Model Number

A-Mode, 10 MHz
B-Mode, 10 MHz

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 (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

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

**Diagnostic Ultrasound Indications for Use Form**

**Page 1 of 1**

**510(k) Number (if known):** K040668

**Device Name: E-Z Scan AB 5500+**

**Intended Use:**

The *E-Z scan AB 5500+* ultrasound system is a multi-purpose computer-based ultrasonic diagnostic system ophthalmic applications, intended to both visualize the interior of the eye by means of ultrasound and to mal measurements inside the eye, including the measurement of axial length for determination of IOL power.

**Mode of Operation**

| CLINICAL APPLICATION | A | B | M | PWD | CWD | COLOR DOPPLER | POWER (AMPLITUDE) DOPPLER | COLOR VELOCITY IMAGING | COMBINED (SPECIFY) | OTHER (SPECIFY) |
|---|---|---|---|---|---|---|---|---|---|---|
| Ophthalmic | P | P | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-operative (specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Specify) | | | | | | | | | | |
| | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | |
| Intra-luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

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

**Additional Comments:**

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

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** ✓ **OR** **Over-the-Counter Use** _____

**(Per 21 CFR 810.109)**

**(Optional Format 1-2-96)**

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K040668

## Diagnostic Ultrasound Indications for Use Form

**Page** 1 **of** ____

**510(k) Number (if known):** K040668

**Device Name: A-Mode Probe E-Z Scan AB 5500+**

**Intended Use:**

The Intended Use of the A_Mode probe for the *E-Z scan AB 5500+* ultrasound system is to make measurements inside the eye, including the measurement of axial length for determination of IOL power, and to visualize the eye by means of A-scans .

**Mode of Operation**

| CLINICAL APPLICATION | A | B | M | PWD | CWD | COLOR DOPPLER | POWER (AMPLITUDE) DOPPLER | COLOR VELOCITY IMAGING | COMBINED (SPECIFY) | OTHER (SPECIFY) |
|---|---|---|---|---|---|---|---|---|---|---|
| Ophthalmic | P | | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-operative (specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Specify) | | | | | | | | | | |
| | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | |
| Intra-luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

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

**Additional Comments:**

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** ✓ **OR** **Over-the-Counter Use** ____

**(Per 21 CFR 810.109)**

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K040668

**(Optional Format 1-2-96)**

## Diagnostic Ultrasound Indications for Use Form

**Page 1 of ____**

**510(k) Number (if known):** K040668

**Device Name: B-Mode Probe, E-Z Scan AB 5500+**

**Intended Use:**

The intended use of the B-Mode probe for the *E-Z scan AB 5500* is to visualize the interior of the eye by means of ultrasound and to make measurements inside the eye by B-scan ultrasound.

**Mode of Operation**

| CLINICAL APPLICATION | A | B | M | PWD | CWD | COLOR DOPPLER | POWER (AMPLITUDE) DOPPLER | COLOR VELOCITY IMAGING | COMBINED (SPECIFY) | OTHER (SPECIFY) |
|---|---|---|---|---|---|---|---|---|---|---|
| Ophthalmic | | P | | | | | | | | |
| Fetal | | | | | | | | | | |
| Abdominal | | | | | | | | | | |
| Intra-operative (specify) | | | | | | | | | | |
| Intra-operative Neurological | | | | | | | | | | |
| Pediatric | | | | | | | | | | |
| Small Organ (Specify) | | | | | | | | | | |
| | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | |
| Cardiac | | | | | | | | | | |
| Trans-esophageal | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | |
| Intra-luminal | | | | | | | | | | |
| Peripheral Vascular | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | |
| Musculo-Skeletal | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |

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

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**Prescription Use** ✓ **OR** **Over-the-Counter Use** ____

**(Per 21 CFR 810.109)**

**(Optional Format 1-2-96)**

David A. Lyerly

**(Division Sign-Off)**
**Division of Reproductive, Abdominal, and Radiological Devices**
**510(k) Number** K040668