K070884

APR 11 2007

StarFish

510(k) Summary
(per 21 CFR 807.92)

I. Applicant

StarFish Product Engineering
#5, 555 Ardersier Road
Victoria, BC V8Z 1C8 Canada

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Date Prepared: January 24, 2007

II. Device Name

Proprietary Name:	POD B-Scan
Common/ Usual Name:	Ophthalmic ultrasonic A and B scan system
Classification Name:	System, Imaging, Ultrasonic, Ophthalmic,
Regulation Number:	892.1560 / 892.1570
Product Codes:	90-IYO / 90-ITX
Classification:	2
Classification Panel:	Radiology

III. Predicate Device

The VuMax High Resolution Ultrasound System manufactured by Sonomed Inc., cleared by FDA (060626) on April 11, 2006.

IV. Intended Use of the Device

The POD B-Scan is intended to be used for visualization by ultrasound of the eye and orbit by A-scan and B-scan.

V. Description of the Device

The POD B-Scan is intended to be used for visualization by ultrasound of the eye and orbit by A-scan and B-scan.

The system is PC-based, and can be used with 35 MHz or 50MHz transducers. Because of the higher frequency of the transducers, it is expected that its greatest field of application will be in visualizing the anterior segment, because the focus area is about 11 mm from the transducer plane. The system can visualize other parts of the eye.

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VI. Summary of the Technical Characteristics

The POD B-Scan is a conventional ophthalmic A and B-scan system using a motor-driven transducer and angle sensor for scanning. The A-scan is derived from the B-scan. There is a choice of transducer frequency of 35 MHz or 50 MHz. It uses a motor-driven 10 MHz transducer with an attached angle encoder. The system is PC-based, and the display is on the computer screen.

VII. Testing

Testing included required ultrasound tests, as well as electrical safety and electromagnetic compatibility tests.

VIII. Conclusion

The POD B-Scan 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 11 2007

Starfish Product Engineering
% Mr. Neil E. Devine, Jr.
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K070884
Trade Name: POD B-Scan
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: March 29, 2007
Received: March 30, 2007

Dear Mr. Devine:

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 POD B-Scan, as described in your premarket notification:

Transducer Model Number

35 MHz
50 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 (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 Ewa Czerska 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)

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: POD B-Scan

Indications for Use:
The POD B-Scan System is a multi-purpose computer-based ultrasound diagnostic system for ophthalmic applications, intended to both visualize the interior of the eye by means of ultrasound and to make measurements inside the eye.

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	N	N								N (3D)
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 Comments: _____

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)

David G. Jogram

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070884

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: POD B-Scan 35 MHz Transducer

Indications for Use:
The POD B-Scan 35 MHz Transducer is for use with the POD B-Scan ultrasound.

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	N	N								N (3D)
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 Comments: _____

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070884

Diagnostic Ultrasound Indications for Use Form

510(k) Number (if known):

Device Name: POD B-Scan 50 MHz Transducer

Indications for Use:
The POD B-Scan 50 MHz Transducer is for use with the POD B-Scan ultrasound.

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic	N	N								N (3D)
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 Comments: _____

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070884