

Special 510(K) Application – PacScan Plus Ophthalmic Ultrasound System  
Section 7 – 510(K) Summary

K092637

**510(K) Summary**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92

Date: July 31, 2009

1. Company and Correspondent making the submission:

Name: Sonomed Inc.  
Address: 1979 Marcus Ave  
Lake Success, NY, 11798  
U.S.A.  
Telephone: 516-354-0900  
Fax: 516-354  
Website: [www.sonomed.com](http://www.sonomed.com)  
Contact: Mr. Charles C. O'Neal, Quality Manager  
E-mail: [coneal@escalonmed.com](mailto:coneal@escalonmed.com)

SEP 24 2009

2. Device:

Trade/proprietary name: PacScan Plus  
Common Name: Diagnostic ultrasound system  
Classification Name: System, imaging, pulsed echo, ultrasonic

3. Predicate Devices:

Manufacturer: Sonomed, Inc.  
Device: 4000P Pachymeter System  
510(k) Number: 123

Manufacturer: Sonomed, Inc.  
Device: E-Z Scan 5500+ A-Scan / B-Scan System  
510(k) Number: 123

4. Classification Names & Citations:

Classification: Class 2  
Classification Code: 21CFR 892.1560, 1570, IYO, ITX, system, imaging, pulsed echo, ultrasonic,

5. Description:

The PacScan™ Plus is the latest generation ophthalmic biometry instrument introduced by industry leading Sonomed. The series consists of two different models:

- o **PacScan™ 300A+**. This A-scan system allows for measuring the axial length (AXL), anterior chamber depth, and lens thickness of an eye and for calculating the associated IOL power for an implanted lens.
- o **PacScan™ 300AP+**. This system seamlessly integrates the A-Scan and Pachymeter capabilities into a single system.

All systems utilize a high-resolution, color backlit touch screen liquid crystal display (LCD) by which the user can enter information and view data and calculations. Each system

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also includes a built-in thermal printer. The system is compact and lightweight thereby making the system extremely portable.

6. Indications for Use:

The PacScan Plus is Sonomed's newest diagnostic ultrasound system which integrates a contact A-scan system, pachymeter, and analog thermal printer into a single unit for the convenient collection and retention of intraocular measurements. The system's principal application is to serve as an aid in the calculation of the associated IOL power for implanted lenses. As such, the PacScan Plus has been designed to capture key measurements such as axial length, anterior chamber depth and corneal thickness with both accuracy and precision.

7. Comparison with predicate device:

Sonomed, Inc. believes that the technologies incorporated into the PacScan Plus are substantially equivalent to those of the 4000P pachymeter system and the E-Z Scan 5500+ A-scan / B-scan system.

8. Safety, EMC and Performance Data:

Electrical, mechanical, environments safety and performance testing according to **standard IEC 60601-1 and IEC 60601-2-37 are currently pending and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All tests results were satisfactory.**

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act 21 CFR Part 807 and based on the information provided in this premarket notification Sonomed, Inc. concluded that the PacScan Plus is safe and effective and substantially equivalent to predicate devices as described herein.

10. Sonomed Inc. will update and include in this summary any other information deemed reasonably necessary by the FDA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Mail Center - WO66-G609  
Silver Spring, MD 20993-0002

Mr. Charles C. O'Neal  
Quality Manager  
Sonomed, Inc.  
1979 Marcus Ave., Suite 105C  
LAKE SUCCESS NY 11042

SEP 24 2009

Re: K092637  
Trade/Device Name: PAC Scan Plus  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulatory Class: II  
Product Code: IYO and ITX  
Dated: August 5, 2009  
Received: August 27, 2009

Mr. O'Neal:

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 PAC Scan Plus, as described in your premarket notification:

Transducer Model Number

A-Mode and Pachymeter

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

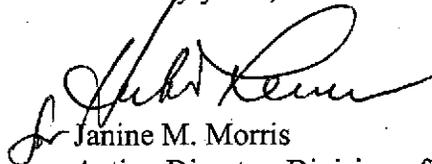
that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (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 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Paul Hardy at (301) 796-6542.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure(s)

Special 510(K) Application – PacScan Plus Ophthalmic Ultrasound System  
**Section 6 – Indications for Use**

510(k) Number (if known): K092637 **Indications for Use**  
 Device Name: Pac Scan Plus

**Indication for Use:**

The PacScan Plus is Sonomed's newest diagnostic ultrasound system which integrates a contact A-scan system, pachymeter, and analog thermal printer into a single unit for the convenient collection and retention of intraocular measurements. The system's principal application is to serve as an aid in the calculation of the associated IOL power for implanted lenses. As such, the PacScan Plus has been designed to capture key measurements such as axial length, anterior chamber depth and corneal thickness with both accuracy and precision.

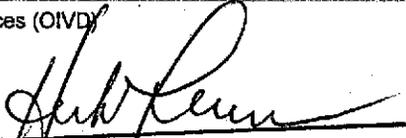
Clinical Application					Mode of Operation			
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							A-Mode and Pachymeter
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Cardiac	Intravascular						
Other (Specify)								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph. (Cardiac)								
Peripheral Vessel	Intra-cardiac							
	Other (Specify)							
	Peripheral vessel							
	Other (Specify)							

Prescription Use (21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off  
 Office of In Vitro Diagnostic Device  
 Evaluation and Safety  
 510(k)  
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 (Division Sign-Off)  
 Division of Reproductive, Abdominal,  
 and Radiological Devices  
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