K043287

DEC 1 0 2004

6.0 Summary of Safety and Effectiveness

Applicant: Micro Medical Devices, Inc.
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Agoura Hills, CA 91301

Correspondent: Rafi Israel, MD
Title: Director of Medical Development
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FDA Registration: 3004574050 [Operator # 9061275]
CA-DHS License: DHS #65371; DHS Contract #2004-04

Device Name

Trade or Proprietary: **PalmScan AP2000 A-Scan/Pachymeter**
Device **PalmScan A2000 A-Scan**
PalmScan P2000 Pachymeter

Common Name: **PalmScan AP2000 Device**
PalmScan A2000 Device
PalmScan P2000 Device

FDA Classification

Classification Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: 2; [Review Category: Tier II]
Regul. Number [Code]: 21 CFR 892.1560 [90-IYO]

Current Device vs. Predicate Device

Device Name	*K Number*	*Decision Date*	*FR Number*	*Product Code*
PalmScan AP2000	TBD	TBD	892.1560	90-IYO
PalmScan A2000	TBD	TBD	892.1560	90-IYO
PalmScan P2000	TBD	TBD	892.1560	90-IYO
DGH 4000 (predicate)	K913067	01/31/1992	892.1560	90-IYO

Description of Device

The PalmScan AP2000 A-Scan/Pachymeter Combination [i.e., PalmScan AP2000] device is a portable, battery operated biometer, which uses A-Mode, pulsed-echo ultrasound technology to measure the axial length (AL), anterior chamber depth (ACD), lens thickness (LT), and corneal thickness (CT) of the human eye. This **PalmScan AP2000** device utilizes a Palm Personal Digital Assistant (Palm PDA) for user interface, information display, as well as data processing. This PalmScan AP2000 device non-sterile professional use only device also utilizes a contact and/or immersion ultrasonic transducer to generate pulses and receive their echoes.

The PalmScan A2000 A-Scan [i.e., PalmScan A2000] device is a portable, battery operated biometer, which uses A-Mode, pulsed-echo ultrasound technology to measure the axial length (AL), anterior chamber depth (ACD), and lens thickness (LT) of the human eye. This **PalmScan A2000** device utilizes a Palm Personal Digital Assistant (Palm PDA) for user interface, information display, as well as data processing. This PalmScan A2000 device non-sterile professional use only device also utilizes a contact and/or immersion ultrasonic transducer to generate pulses and receive their echoes.

The PalmScan P2000 Pachymeter [i.e., PalmScan P2000] device is a portable, battery operated biometer, which uses A-Mode, pulsed-echo ultrasound technology to measure the corneal thickness (CT) of the human eye. The **PalmScan P2000** device utilizes a Palm Personal Digital Assistant (Palm PDA) for user interface, information display, as well as data processing. This PalmScan P2000 device non-sterile professional use only device also utilizes a contact and/or immersion ultrasonic transducer to generate pulses and receive their echoes.

Indications for Use:

Collectively, the **3 PalmScan 2000 Devices** [i.e., three (3) biometric devices listed below] are each designed as either: a) the PalmScan AP2000 A-Scan/Pachymeter Combination dual mode device [i.e., **PalmScan AP2000**]; or solely as: b) the PalmScan A2000 A-Scan mode only device [i.e., **PalmScan A2000**]; or as: c) the PalmScan P2000 Pachymeter mode only [i.e., **PalmScan P2000**] medical device.

The PalmScan AP2000 A-Scan/Pachymeter Combination [i.e., **PalmScan AP2000**] device is intended as a portable battery operated biometer, which incorporates A-mode pulsed-echo ultrasound technology, and thus is intended be used to accurately measure the axial length (AL), anterior chamber depth (ACD), lens thickness (LT), and corneal thickness (CT) of the human eye. This **PalmScan AP2000** device is also intended for calculating the optical power of an intraocular lens (IOL) that is to be implanted during cataract surgery.

The PalmScan A2000 A-Scan [i.e., **PalmScan A2000**] device is intended as a portable battery operated biometer, which incorporates A-mode pulsed-echo ultrasound technology, and thus is intended be used to accurately measure the axial length (AL), anterior chamber depth (ACD), and lens thickness (LT) of the human eye. This **PalmScan A2000** device is also intended for calculating the optical power of an intraocular lens (IOL) that is to be implanted during cataract surgery.

The PalmScan P2000 Pachymeter [i.e., **PalmScan P2000**] device (as well as the combination **PalmScan AP2000** device) is intended as a potable battery operated pachymeter, which incorporates A-mode pulsed-echo ultrasound technology, and thus is intended be used to accurately measure the corneal thickness (CT) of the human eye.

Each of the **3 PalmScan 2000 Devices** [i.e., **PalmScan AP2000** combination device; **PalmScan A2000** A-Scan device; and/or **PalmScan P2000** pachymeter device] is intended to be used solely by qualified medical professionals. Clinical considerations and professional judgment should be applied when using this or any other testing device used for patient diagnosis or treatment.

Predicate Device Comparison

PalmScan AP2000, A2000, & P2000 devices, and the DGH-4000 [DGH Technology, Exton, PA 19341; K913067; cleared 01/31/92] device are each based on ultrasonic pulse echo technology, whereby short bursts of ultrasonic energy are transmitted and the resulting echoes are captured, amplified, filtered, and processed. Time differences in captured echo peaks are measured and converted into distance information. Digital signal processing algorithms validate individual peaks and the resulting measurements are displayed for the medical professional user.

Discussion of Non-Clinical Tests

PalmScan A2000, P2000 and AP2000 models have been tested for accuracy, ultrasonic emissions and software validation, according to the requirements identified in: ***FDA-"Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers"***, FOD #560, Sept. 30, 1997; and ***FDA -"510(k) Guide for measuring and reporting acoustic output of diagnostic ultrasound medical devices"***, US Dept. Health and Human Services, FDA, 1992; as well as in ***FDA –"Guidance for Off-the-Shelf Software Use in Medical Devices; Final"***, FOD # 585, September 9, 1999; ***FDA – "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Final"***, FOD # 337, May 29, 1998; ***FDA - "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review"***, US Dept. Health and Human Services, FDA 1991.

Discussion of Clinical Tests

Not required.

Table A – Comparative Table of Similarities for PalmScan 2000 Devices vs. DGH-4000 Device

Category	PalmScan 2000 Devices	DGH 4000 Device
Indications for use	Collectively, the **PalmScan 2000 Devices** [i.e., three (3) biometric devices listed below] are each designed as either a) the PalmScan AP2000 A-Scan/Pachymeter Combination dual mode device [i.e., **PalmScan AP2000**]; or solely as: b) the PalmScan A2000 A-Scan mode only device [i.e., **PalmScan A2000**]; or as: c) the PalmScan P2000 Pachymeter mode only [i.e., **PalmScan P2000**] medical device. The PalmScan AP2000 A-Scan/ Pachymeter Combination [i.e., **PalmScan AP2000**] device is intended as a portable battery operated biometer, which incorporates A-mode pulsed-echo ultrasound technology, and thus may be used to accurately measure the axial length (AL), anterior chamber depth (ACD), lens thickness (LT), and corneal thickness (CT) of human eye. This PalmScan AP2000 device is also intended for calculating the optical power of an intraocular lens (IOL) that is to be implanted during cataract surgery. The PalmScan A2000 A-Scan [i.e., **PalmScan A2000**] device is intended as a portable battery operated biometer, which incorporates A-mode pulsed-echo ultrasound technology, and thus may be used to accurately measure the axial length (AL), anterior chamber depth (ACD), and lens thickness (LT) of human eye. This PalmScan A2000 device is also intended for calculating the optical power of an intraocular lens (IOL) that is to be implanted during cataract surgery.	The DGH 4000 device instrument is used for measuring the axial length, (AL) anterior chamber depth (ACD), lens thickness (LT) and corneal thickness (CT) of the human eye. This device may also be used to calculate the optical power of the intraocular lens (IOL) that is to be implanted during cataract surgery.

	The PalmScan P2000 Pachymeter [i.e., **PalmScan P2000**] device is intended as a portable battery operated biometer, which incorporates A-mode pulsed-echo ultrasound technology, and thus may be used to accurately measure the corneal thickness (CT) of human eye. PalmScan 2000 Devices [i.e., PalmScan AP2000 device; PalmScan A2000 A-Scan device; and/or PalmScan P2000 Pachymeter device] are to be used solely by qualified medical professionals. Clinical considerations and professional judgment should be applied when using this or any other testing device used for patient diagnosis or treatment.	
General Device Description	Ultrasonic pulse echo imaging system	Ultrasonic pulse echo imaging system
A-Scan Transducer type	Solid	Solid
Pachymeter transducer type	Solid	Solid
Data storage and review	Storage of measurement data for review.	Storage of measurement data for review.
Audible indications	Audible signal indicates when a valid measurement is complete	Audible signal indicates when a valid measurement is complete
Automatic data capture	A-Scan Pattern recognition program yields accurate reproducible measurements.	A-Scan Pattern recognition program yields accurate reproducible measurements.
IOL calculation	SRK II, SRK/T, HfrQ	SRK II, SRK/T, HofferQ

Table B – Comparative Table of Differences for PalmScan 2000 Devices vs. DGH-4000 Device

Category	PalmScan 2000 Devices	DGH 4000 Device
Display	Hi resolution, color graphic LCD that displays AL, LT and ACD.	Large 32 char Alpha Numeric display that displays AL, LT and ACD.
Keyboard interface	Full keyboard + touch screen LCD	Front panel keyboard
Printing	Wireless network printer or infrared printer documents A-Scan and Pachymeter results and IOL calculations.	Built in printer documents A-Scan and Pachymeter results and IOL calculations.
Power source	Totally portable and battery operated	Needs 110-220 VAC
Shipping weight	2 lb	15 lbs
Weight	10 ounces	12 lbs
Dimensions	Height 0.6", Width 5.75", Depth 3.3"	Height 5.5 ", Width 12.5 ", Depth 12 "
Power Consumption	3.6 V-920MAH rechargeable battery. 110-120 or 200-240 VAC, 50-60Hz Charger	110-120 or 200-240 VAC, 50-60Hz
Battery operations	Battery operated	Not battery operated

Table C – Acoustic power output for PalmScan 2000 Devices vs. DGH-4000 Device

Maximum acoustic output (In-Situ)	PalmScan AP & A 2000 (A-Scan)	PalmScan AP & P 2000 Pachymeter	DGH A-Scan	DGH Pachymeter
ISPTA.3 (mW/cm2)	0.419	0.088	1.66	7.47
ISPPA.3 (W/cm2)	0.795	0.29	2.76	12.0

The PalmScan 2000 devices put out much less acoustical power output (milli-Wattage) when compared to the predicate DGH-4000 device in both A-Scan and pachymeter modes. Thus, the PalmScan 2000 devices meet the IEC electrical & power standards set in IEC-60601-1 Standard, and are well below the acoustical power limits set forth by *FDA-"Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers"*, FOD #560, Sept. 30, 1997, and are thus safe for use upon human ocular tissues.

Table D – Comparison General Safety and Effectiveness

Category	PalmScan 2000 Devices			DGH 4000 Device		
A-Scan Mode	**Range**	**Accuracy**	**Display Resolution**	**Range**	**Accuracy**	**Display Resolution**
Axial Length	15.0 – 39.0 mm	± 0.1 mm	0.01	15.0 - 34.0 mm	± 0.1 mm	0.01 mm
Anterior Chamber Depth	1.8 – 6.0 mm	± 0.1 mm	0.01	2.0 – 6.0 mm	± 0.1 mm	0.01 mm
Lens Thickness	2.0 – 7.5 mm	± 0.1 mm	0.01 mm	2.0 – 7.5 mm	± 0.1 mm	0.01 mm
Pachymeter Mode	**Range**	**Accuracy**	**Display Resolution**	**Range**	**Accuracy**	**Display Resolution**
Corneal Thickness	105-1590 μm	± 3.5 μm	1 μm	200 – 1300 μm	± 5.0 μm	1 μm

Clinical Measurement Accuracy and System Sensitivity

Clinical accuracy of the PalmScan AP2000, A2000, and P2000 is dependent on a number of conditions, these conditions are:

1. Indentation of cornea during the contact biometry.
2. Jitter associated with the operators hand during contact biometry.
3. Movement of the patient's eye during measurements.

The contact method for AL measurement does not yield the same results as the high precision A-scan biometry. When measuring the same eye, the contact technique yields a shorter measurement than the immersion technique.[12-14]

In order for the operator to have an idea about how accurate are his or her measurements, the, PalmScan AP2000 and A2000 displays a Standard Error of the Mean (SEM) based on sets of captured waveforms. In this example, with average axial length of 25.71 mm and SEM of 0.03 mm, one obtains a desired confidence interval of 95%.

Table E-1 – Estimated Mean Error for the A-Scan Mode

Confidence Interval	Mean Error
90%	mean ± 1.64*SEM
95%	mean ± 1.96*SEM
99%	mean ± 2.58*SEM

Clinical Accuracy of this measurement with either the PalmScan AP2000 device or the PalmScan A2000 A-Scan device; is with 95% certainty that the range of axial length/AL of this human volunteer has been determined to be:

$$AL = 25.71 \pm (1.96*0.03)\ mm = 25.71 \pm 0.059\ mm$$

Similar technique could be applied to Pachymeter calculations using the PalmScan AP2000. Hence clinical accuracy could be estimated for each measurement.

In order to improve the accuracy of the PalmScan AP2000, P2000 and A2000 devices, the PalmScan designers employed a technique commonly used in high speed digitizing Oscilloscopes. This technique is known as "digital-Over-Sampling". By setting the over sampling rate to 4 in A-Scan mode and 8 in Pachymeter mode, the devices accuracy has been vastly improved.

In the A-Scan mode of operation, the range, accuracy and resolutions of the PalmScan AP2000 are as noted in the table below:

Table E-2 – PalmScan A-Scan Range, Accuracy & Resolution

AP2000 & A2000 (in A-Scan Mode)	Range	Spatial Accuracy	Temporal Accuracy	Display Resolution
Axial Length (mm)	15.0 – 35.0	± 0.038	± 0.007	0.01
Anterior Chamber Depth (mm)	1.8 – 6.0	± 0.038	± 0.007	0.01
Lens Thickness (mm)	2.0 – 7.5	± 0.038	± 0.007	0.01

In the A-Scan mode of operation, the PalmScan AP2000 and A2000 were tested extensively with eye phantoms. The eye phantom was purchased from DGH Corporation. This eye phantom was calibrated to measure an aphakic eye of 24.1 ± 0.25 mm. Next, the PalmScan AP2000 and A2000 devices were set to aphakic data capture mode and multiple measurements were taken from the DGH phantom. Eye phantom tests confirmed the results to be within specified tolerances.

In the Pachymeter mode of operation, the PalmScan AP2000 and P2000 devices were tested extensively with eye phantoms. The range, accuracy and resolutions of the PalmScan AP2000 and P2000 are as noted in the table below (with all results displayed in microns = μm).

Table E-3 – Pachymeter Range, Accuracy and Resolution

AP2000 & P2000 (in Pachymeter Mode)	Range	Spatial Accuracy	Temporal Accuracy	Display Resolution
Corneal Thickness (μm)	105-1590	$\pm$ 20.5	$\pm$ 3.1	1

The PalmScan AP2000 and P2000 devices were also tested extensively with a pachymeter eye phantom. The eye phantom for this test was created in house using a fixed delay circuit. The delay in this delay circuit was first measured using a calibrated Oscilloscope and then tested with the PalmScan AP2000 and P2000 in the Pachymeter mode. Conclusion: The eye phantom tests confirmed the results to be within the specified tolerances.

Table F– Compliance Tests for PalmScan 2000 Devices

Compliance Test	Agency Name	Project Number	Contact Number
IEC 60601-1-1	**TUV-Rheinland**	**30492391.001**	**818-739-1122**
IEC 60601-2-37	**TUV-Rheinland**	**30492391.001**	**818-739-1122**
IEC 60601-1-2	**JMR Electronics**	**040960-1**	**818-739-1122**

Software Specification & Support Data - PalmScan 2000 Devices

Software that governs the operation of diagnostic ultrasound equipment is a minor level of concern, as described in: ***FDA –"Guidance for Off-the-Shelf Software Use in Medical Devices; Final"***, FOD # 585, September 9, 1999; ***FDA –"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Final"***, FOD # 337, May 29, 1998; as well as ***FDA -"Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review"*** **(FDA 1991).** This is due to the fact that the potential for injury possible to a patient in the event of software/firmware failure, both direct (i.e., inappropriate delivery of electrical, thermal, or acoustic energy) and indirect (i.e., inappropriate physician action based on inaccurate diagnostic information), is not likely to be major or life threatening.

Table G – Accuracy calculations for PalmScan 2000 Devices

Parameter	*A-Scan Mode*	*Pachymeter Mode*
Relevant Speed of Sound (m/s)	1530	1640
Sampling rate (MHz)	132	264
Accuracy (+/- microns = μm)	5.75	3.1

Table H- Potential Hazardous Events- PalmScan 2000 Devices

Potential Hazardous Event	Level of Concern	Cause/Control/ and Corrective Measure
Measurement Hazards	Minor	Discussed in Section 4.7.5.4.1
Mechanical Hazards	Minor	Discussed in Section 4.7.5.4.2
Radiation Hazards	Minor	Discussed in Section 4.7.5.4.3

Here follow examples of hazards analyses that were carried out:

Potential Measurement errors – due to possible Digital clock error (i.e. drift and aging)

PalmScan 2000 devices use a high precision crystal oscillator. This oscillator is specified to have drift and aging errors. This drift error covers the entire operating temperature range (18-40 degrees °C) for PalmScan devices. Aging defines how this measured frequency will vary with age.

Level of Concern - Table Q shows these errors to be of negligible magnitude in the calculation of axial length and corneal thickness and are therefore of minor level of concern.

Table I- Oscillator Errors Estimated for the PalmScan Devices

Error Type	A-Scan Predicted Error	Pachymeter Predicted Error
Drift	**2.3 micron (μm)**	**0.055 micron (μm)**
Aging	**0.35 microns/yr**	**0.00825 microns/yr**

Cause of Hazard - Drift and Aging errors are an inherent part of an operation of any crystal oscillator.

Method of Control - High precision oscillators were selected to minimize aging and drift errors.

Corrective Measures - High precision clock components are used in the design of PalmScan AP2000, A2000 and P2000 to ensure minimal measurement errors due to clock inaccuracies.

Testing - Measurement tests of accuracy using the PalmScan AP2000, A2000 in A-Scan mode were performed both with a standard phantom and confirmed by comparison study of our measurements in four human eyes against a laser interferometer method *(using the Zeiss IOL Master device; K993357; cleared: 03/20/2000).* Laser interferometry via such devices is considered a gold standard in axial length measurement by ophthalmologists.

In-house measurement tests of accuracy using the PalmScan AP2000, and PalmScan P2000 in the Pachymeter mode were performed both with a standard phantom and confirmed by comparison studies in human eyes against a high precision Pachymeter. In all case, comparison results confirmed the expected accuracies [here listed in microns or μm].

Table J – PalmScan AP2000, P2000 vs. IOL-Master comparison

Eye #	Immersion PalmScan A-Mode Results	IOL-Master Results
1	25.65 μm	25.66 μm
2	25.75 μm	25.72 μm
3	23.15 μm	23.16 μm
4	23.20 μm	23.18 μm

Potential for Hardware Failure Causing Measurement Hazards

Although unlikely, PalmScan 2000 system hardware failures may cause measurement errors and hazards.

Level of Concern - PalmScan 2000 device failure is of a minor level of concern because controls and corrective measures have been put into place to reduce such risk.

Hardware Failure causing measurement errors - Failures in the PalmScan 2000 device hardware can cause errors of two types:

1. Failure causing data not to be sent to the Palm device.
2. Failure causing invalid data to be sent to the Palm device.

Method of Control - When the PalmScan 2000 is initially activated, the system performs a self-test sequence. During this process, proper operation of the device's major components is checked. This process ensures the proper functionality of the system. Although unlikely, it is foreseeable that a unit could pass the self test sequence and still not be fully functional. In these situations, there are two possible outcomes:

1. No data is being sent to the Palm device.
2. Invalid data is being sent to Palm device.

In either of these two situations noted above, the software pattern recognition algorithm will not recognize the data as valid and the data will be rejected.

Corrective Measures - In the A-Scan mode, the user is instructed in the device operations manual to review the captured waveforms and decide whether they are valid. In addition, the data review algorithm performs statistical analysis of data and color codes the results in the A-Scan mode. The operators are instructed to review and are recommended to reject red coded captures. This procedure minimizes the risk involved in invalid data captures caused by hardware failure.

For device usage in the pachymeter mode, the PalmScan AP2000 and P2000 operations user manual recommends that the user review data waveforms and decide whether these data are valid. The data sets obtained are statistically analyzed and only data with standard deviations less than 5 microns are captured. This process minimizes the risk of invalid data captures due to hardware failure.

Biocompatibility Evaluation

As evaluated according to standard protocols *[ISO – 10993-10:1995 - **"Biological evaluation of medical devices -- Part 10: Tests for irritation and sensitization"** [Used for medical devices requiring skin irritation or ocular irritation testing per ANSI/AAMI/ISO 10993-1), Publ.: ISO, Geneva, Switzerland, 1995]*, the contact tip of the PalmScan AP2000 is made of Polystyrene in Pachymeter mode and Epoxy in A-Scan mode. The chemical composition, physical parameters, and especially the biocompatibility characteristics of the PalmScan AP2000, A2000 and P2000 ocular contact tips have shown themselves to be non-irritating and completely safe with human ocular tissues. **(see section 8 for certification)**

Conclusion of Non-Clinical Tests

In the above mentioned non-clinical data measurements and tests, this new PalmScan AP2000, A2000 and P2000 devices and the cleared predicate DGH-4000 device were evaluated against the same eye phantoms and similar measurements were acquired. Thus, based on the results of these non-clinical tests, the new PalmScan AP2000, A2000 and P2000 devices were demonstrated to be substantially equivalent/SE to the cleared predicate DGH-4000 device.

Summary & Conclusions

In all the above non-clinical tests, verifications, validations, and data measurements, the PalmScan AP2000, A2000 and P2000 devices have been demonstrated to be substantially equivalent/SE for safety and effectiveness in all performance evaluations when compared to the cleared predicate DGH-4000 device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 10 2004

Micro Medical Devices, Inc.
% Alfredo J. Quattrone, Ph.D., D.A.B.T.
Third Party 510(k) Review Coordinator
California-Health and Human Services
Food and Drug Branch
PO Box 997413, Mail Stop-7602
SACRAMENTO CA 95899-7413

Re: K043287
Trade Name: PalmScan AP2000 A-Scan/Pachymeter Combination Device, PalmScan A2000 A-Scan Device, PalmScan P2000 Pachymeter Device
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imagingsystem
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYO and ITX
Dated: November 24, 2004
Received: November 29, 2004

Dear Dr. Quattrone:

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 PalmScan AP2000 A-Scan/Pachymeter Combination Device, PalmScan A2000 A-Scan Device, PalmScan P2000 Pachymeter Device, as described in your premarket notification:

Transducer Model Number

10 MHz A-Scan
20 MHz 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 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

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

Sincerely yours,

David A. Segroves

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

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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 Comments: PalmScan AP2000 A-Scan/Pachymeter Combination Device

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, **Abdominal,**
and Radiological Devices
510(k) Number K043287

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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 Comments: PalmScan A2000 A-Scan Device

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043287

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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 Comments:

PalmScan P2000 Pachymeter Device

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043287

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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 Comments: A-Scan 10 MHz Transducer

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lepsen

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K043787

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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 Comments: Pachymeter 20 MHz Transducer

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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510(k) Number K043287