K050980

MAY 26 2005

510(k) SUMMARY

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Paradigm Medical Industries, Inc.
2355 South 1070 West
Salt Lake City, Utah 84119
Phone: (801) 977-8970
Fax: (801) 977-8973

Contact Person: Edward A. Kroll
Representative Consultant for
Paradigm Medical Industries, Inc.
5905 Fawn Lane
Cleveland, Ohio 44141
Phone: (440) 546-9810
Fax: (440) 546-9124

Date Prepared April 15, 2005

Name of Device

Model P60 Ultrasonic Bio-Microscope

Common or Usual Name

Ultrasound System

Classification Name

Ultrasonic Pulsed Echo Imaging System

Predicate Devices

Paradigm Medical Model P45 Ultrasonic Bio-Microscope

Intended Use

To acquire and display high resolution images of the anterior segment of the eye.

Device Description

The Model P60 UBM is a PC-based digital instrument that utilizes ultrasonic energy to generate various images of the eye. The pulser circuitry is designed to accept information from the user via a graphical user interface provided by the software. The pulser generates signals specific to the probe installed. The signal acquired from the transducer is translated into an image that is displayed on an LCD monitor.

Performance Data

The Model P60 UBM has been tested to and meets the applicable requirements of IEC60601-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Paradigm Medical Industries, Inc.
c/o Mr. Edward A. Kroll
President
Spectre Solutions, Inc.
5905 Fawn Lane
CLEVELAND OH 44141

MAY 26 2005

Re: K050980
Trade Name: Paradigm Medical Model P60 Ultrasonic Bio-Microscope
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: IYO
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: ITX
Regulatory Class: II
Dated: April 15, 2005
Received: April 21, 2005

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 Paradigm Medical Model P60 Ultrasonic Bio-Microscope as described in your premarket notification:

Transducer Model Numbers

B-Scan (10 MHz)	B-Scan (20 MHz)	35 MHz Water-Path	50 MHz Water-Path

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/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Mr. 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

Enclosures

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: **Model P60**
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-skelatal Superficial										
Other (Specify)										

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

Additional Comments: Sulcus-to-sulcus imaging

(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

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050980

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: _____

Transducer: **B-Scan (10 MHz)**

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-skelatal Superficial										
Other (Specify)										

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

Additional Comments: _____

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

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050980

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: _____

Transducer: **B-Scan (20 MHz)**

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-skelatal Superficial										
Other (Specify)										

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

Additional Comments: _____

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

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K050980

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: ______________________

Transducer: **35 MHz Water-Path**

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-skelatal Superficial										
Other (Specify)										

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

Additional Comments: ______________________

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

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050980

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: _____

Transducer: **50 MHz Water-Path**

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-skelatal Superficial										
Other (Specify)										

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

Additional Comments: _____

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

David A. Lagowski

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050980

Prescription Use (Per 21 CFR 801.109)