



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 7 2005

Mediwatch Ltd.
% Mr. Jeffrey D. Rongero
UL International (UK) Ltd. Domestic Correspondent
Underwriters Laboratories, Inc.
Research Triangle Park Division
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709-3995

Re: K053325

Trade Name: Mediwatch Multiscan Ultrasound System / Scanner
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: November 17, 2005
Received: December 1, 2005

Dear Mr. Rongero:

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 Mediwatch Multiscan Ultrasound System / Scanner, as described in your premarket notification:

Transducer Model Number

Abdominal 3.5/5.0 MHz
Endocavity EF 5.0/7.5 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.

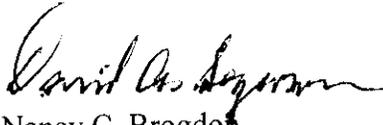
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 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(s)

Diagnostic Ultrasound Indications for Use Form

System: Multiscan

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

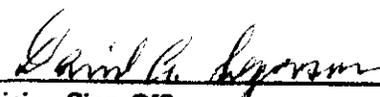
Clinical application	Mode of Operation								
	A	B	M	PWD (D)	Colour Doppler (AD)	Amplitude Doppler (AD)	Colour Velocity Imaging	Combined (specify)	Other (Specify)
Ophthalmic									
Fetal									
Abdominal		N							
Intraoperative (specify)									
Intraoperative Neurological									
Paediatric									
Small Organ (Testes)		N							
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transophageal									
Transrectal		N							Note 1
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular									
Laparoscopic									
Musculoskeletal Conventional									
Musculoskeletal Superficial									
Other (specify)									

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

Additional Comments: Note 1 Included in this 510K is imaging to assist in the guidance of a biopsy needle.

(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)



 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K053325

Diagnostic Ultrasound Indications for Use Form

System: Multiscan Transducer: Abdominal 3.5/5.0MHz

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

Clinical application	Mode of Operation							Combined (specify)	Other (Specify)
	A	B	M	PWD (D)	Colour Doppler (AD)	Amplitude Doppler (AD)	Colour Velocity Imaging		
Ophthalmic									
Fetal									
Abdominal		N							
Intraoperative (specify)									
Intraoperative Neurological									
Paediatric									
Small Organ (Testes)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular									
Laparoscopic									
Musculoskeletal Conventional									
Musculoskeletal Superficial									
Other (specify)									

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Additional Comments: _____

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Symon

(Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number K053325

Diagnostic Ultrasound Indications for Use Form

System: Multiscan Transducer: Endocavity EF 5.0/7.5MHz

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

Clinical application	Mode of Operation							Combined (specify)	Other (Specify)
	A	B	M	PWD (D)	Colour Doppler (AD)	Amplitude Doppler (AD)	Colour Velocity Imaging		
Ophthalmic									
Fetal									
Abdominal									
Intraoperative (specify)									
Intraoperative Neurological									
Paediatric									
Small Organ (Testes)		N							
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transophageal									
Transrectal		N							Note 1
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular									
Laparoscopic									
Musculoskeletal Conventional									
Musculoskeletal Superficial									
Other (specify)									

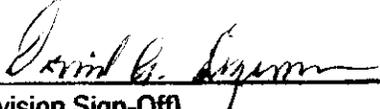
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)



 (Division Sign-Off)
 Division of Reproductive, Abdominal,
 and Radiological Devices
 510(k) Number 2053325