DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 4 2003

Mediwatch, plc
% Ms. Susan Gill
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
P.O. Box 13995
Research Triangle Park, NC 27709

Re: K033906
Trade Name: Portascan Bladder 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: 90 IYO and ITX
Dated: December 16, 2003
Received: December 17, 2003

Dear Ms. Gill:

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 transducer intended for use with the Portascan Bladder Scanner, as described in your premarket notification:

Portascan Probe (3.5 MHz/5.0 MHz Transabdominal & Bladder)

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 (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.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

Portascan System

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

	Mode of Operation								
Clinical application	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 (Specify)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transophageal									
Transrectal									
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

Prescription Use (Per 21 CFR 892.1560/70)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033906

510(k) Number (if known): _____

Device Name: _____

Indications For Use: _____

Diagnostic Ultrasound Indications for Use Form

System: Portascan Probe (manufactured by Pie Medical 510(k) number K020112).

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

Mode of Operation									
Clinical application	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 (Specify)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Transophageal									
Transrectal									
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

Prescription Use (Per 21 CFR 892.1560/70)

Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033906

510(k) Number (if known): _____

Device Name: _____

Indications For Use: _____