



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2008

Laborie Medical Technologies, Corporation
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K081781

Trade/Device Name: NuWay Ultrasound Probe System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: OYN, IYO, and ITX
Dated: June 23, 2008
Received: June 24, 2008

Dear Mr. Job:

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 NuWay Ultrasound Probe System, as described in your premarket notification:

Transducer Model Number

GP 3.5 MHz

GP 5.0 MHz

SP 7.5 MHz

SF 7.5 MHz

MV 12 MHz

EC 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 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" (21 CFR 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 (240) 276-3150 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 Lauren Hefner at (240) 276-3666.

Sincerely yours,



En Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K081781

Device Name: NuWav Ultrasound Probe System

The NuWav Ultrasound Probe System is intended to be used to perform diagnostic general ultrasound studies including Fetal, Abdominal (Solid Organs, Aneurysms, bladder), Pediatric, Small organ (breast, thyroid, bladder, testes, prostate), Neonatal Cephalic, Cardiac, Trans-vaginal, Trans-rectal, Peripheral Vascular, and Musculoskeletal (Conventional and Superficial). The system provides imaging for guidance of biopsy and imaging to assist in the placement of needles or other anatomical structures as well as performing Urodynamic Studies.

For Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081781

**SECTION 4.3
INDICATIONS FOR USE**

Ultrasound Device Indications For Use

510(k) Number:

Device Name: NuWav Ultrasound Probe System

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

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Ophthalmic										
Fetal		N								Note 3
Abdominal		N								Note 1 Note 3
Intra-Operative (Specify) (See note 4)										
Intra-Operative Neurological										
Pediatric		N								Note 3
Small Organ		N								Note 3 Note 2
Neonatal Cephalic		N								
Adult Cephalic										
Cardiac		N								
Transesophageal										
Trans-Rectal		N								Note 3
Trans-Vaginal		N								Note 3
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		N								
Laparoscopic										
Muscular-Skeletal Conventional		N								
Muscular-Skeletal Superficial		N								
Others (Specify)										

N=1 New Indication

Note 1: Abdominal, Solid organs, Aneurysms, Bladder.

Note 2: Small Organ: breast, thyroid, testes, prostate.

Note 3: includes imaging for guidance of biopsy

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Indications for Use

Division of Reproductive, Abdominal and Radiological Devices

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510(k) Number K081781

Ultrasound Device Indications For Use

510(k) Number:

Device Name:

NuWav Ultrasound Probe System

Transducer:

GP 3.5 MHz Mechanical Sector Probe

Indications for Use:

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

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Ophthalmic										
Fetal		P								
Abdominal		P								Note 1 Note 3
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ		P								Note 2
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral-Vascular										
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

P=Previously Cleared, in K951978 and referenced K070907

Note 1: Abdominal, Solid organs, Aneurysms, Bladder.

Note 2: Small Organ: breast, thyroid, testes, prostate.

Note 3: Includes Imaging for guidance of biopsy

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Indications for Use

510(k) Number K081781

Ultrasound Device Indications For Use

510(k) Number:

Device Name:

NuWav Ultrasound Probe System

Transducer:

GP 5.0 MHz Mechanical Sector Probe

Indications for Use:

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

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Ophthalmic										
Fetal		P								
Abdominal		P								Note 1 Note 3
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ		P								Note 2
Neonatal Cephalic		P								
Adult Cephalic										
Cardiac		P								
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral Vascular										
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

P=Previously Cleared in K951976 and referenced K070907

Note 1: Abdominal, Solid organs, Aneurysms, Bladder.

Note 2: Small Organ: breast, thyroid, testes, prostate.

Note 3: Includes Imaging for guidance of biopsy

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Indications for Use

Division of Reproductive, Abdominal and Radiological Devices

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510(k) Number K081781

Ultrasound Device Indications For Use

510(k) Number:
Device Name: NuWav USB Ultrasound Probe System
Transducer: SP 7.5 MHz Mechanical Sector Probe

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

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P								Note 3
Intra-Operative										
Intra-Operative Neurological										
Pediatric										
Small Organ		P								Note 2
Neonatal Cephalic		P								
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P								
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

P=Previously Cleared in K951976 and referenced K070907

Note 2: Small Organ: breast, thyroid, testes, prostate.

Note 3: Includes imaging for guidance of biopsy

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Indications for Use

510(k) Number K081781

Ultrasound Device Indications For Use

510(k) Number:
 Device Name: NuWav USB Ultrasound Probe System
 Transducer: SF 7.5 MHz Mechanical Sector Probe

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

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ										Note 2 Note 3
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal		P								Note 3
Trans-Vaginal		P								Note 3
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P								
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

P=Previously Cleared K951976 and referenced K070907

Note 2: Small Organ: breast, thyroid, testes, prostate.

Note 3: Includes imaging for guidance of biopsy

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Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K081781

Indications for Use

Ultrasound Device Indications For Use

510(k) Number:
 Device Name: NuWav Ultrasound Probe System
 Transducer: MV 12 MHz Mechanical Sector Probe

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

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative (Specify)										
Intra-Operative Neurological										
Pediatric										
Small Organ		P								Note 2 Note 3
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P								Note 3
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

Previously Cleared; K070907

Note 2: Small Organ: breast, thyroid, testes, prostate.

Note 3: Includes imaging for guidance of biopsy

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Indications for Use

510(k) Number K081781

Ultrasound Device Indications For Use

510(k) Number:
Device Name: NuWav Ultrasound Probe System
Transducer: EC 7.5 MHz Mechanical Sector Probe

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

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B - M)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative										
Intra-Operative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal		P								Note 3
Trans-Vaginal		P								Note 3
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others (Specify)										

P=Previously Cleared, K951976 and referenced K070907
 Note 3: Includes imaging for guidance of biopsy

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Indications for Use

Division of Reproductive, Abdominal and Radiological Devices
 510(k) Number K081781