



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Spencer Newman
President
Newman Medical
42 Sherwood Ter, Ste 2
LAKE BLUFF IL 60044

MAY 12 2011

Re: K110628
Trade/Device Name: simpleABI
Regulation Number: 21 CFR 892.1540
Regulation Name: Nonfetal ultrasonic monitor
Regulatory Class: II
Product Code: JAF and ITX
Dated: April 12, 2011
Received: April 14, 2011

Dear Mr. Newman:

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 simpleABI, as described in your premarket notification:

Transducer Model Number

5 MHz
8MHz
PPG

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 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

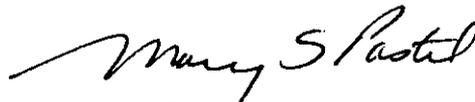
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Robert Ochs, Ph.D. at (301) 796-6661.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use Form

510(k) Number (if known): TBD

Device Name: simpleABI

Indications for Use:

The simpleABI is a diagnostic ultrasound system used to aid a physician in obtaining systolic pressure values at the arms and legs to aid in the diagnosis of vascular disease. The system utilizes a handheld Doppler for detecting presence or absence of blood flow. The user, using a handheld aneroid, Doppler, and standard blood pressure cuffs, measures the systolic pressures of the arms and legs. Two additional modalities, Pulse Volume Recording (PVR) and Photoplethysmography (PPG), may optionally provide additional information for the clinician. PVR is used as a plethysmograph to measure the change in limb volume related to each cardiac pulse. The PPG may be used to obtain toe pressures as an optional method if arterial flow using a Doppler is problematic. The unit will calculate Ankle Brachial Index (ABI), Toe Brachial Index (TBI) or segmental values once the clinician has entered the appropriate pressure values read from the handheld aneroid. Waveforms, pressure values, and index results can be printed directly from the system.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Patel
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110628

Diagnostic Ultrasound Indications for Use Form

Product Name: simpleABI with 5 MHz, 8 MHz, or PPG probe.

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										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

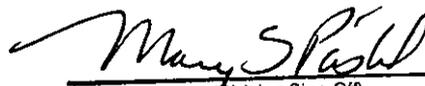
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The system consists of a main body and one probe. The 5MHz, 8MHz, or PPG probes are designed for peripheral vascular applications.

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)



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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110628

Diagnostic Ultrasound Indications for Use Form

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

Product Name: simpleABI 5MHz

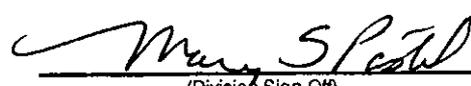
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: The nominal 5MHz probe previously submitted and approved under K090465

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)
 Prescription Use (Per 21 CFR 801.109)


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 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110628

Diagnostic Ultrasound Indications for Use Form

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

Product Name: simpleABI 8MHz

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

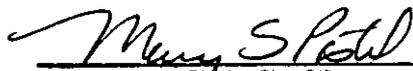
Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: The nominal 8MHz probe previously submitted and approved under K090465

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Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)

Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110028

Diagnostic Ultrasound Indications for Use Form

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

Product Name: simpleABI PPG

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										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

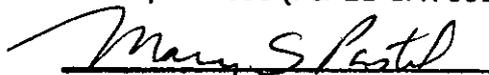
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The PPG probe is intended for vascular applications to determine blood flow in digits.

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Prescription Use (Per 21 CFR 801.109)


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510K B110628