K123565

1.8. 510(k) Summary

DEC 13 2012

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 as implemented in 21 C.F.R. §807.92 (c).

The assigned 510(k) number is: _____

Date Prepared:	October 26, 2012
Establishment:	PhysioSonics, Inc. 2002 156th Ave NE, Suite #150 McKinley Building Bellevue, WA 98007 Phone: 425.732.2814 Fax: 425.732.2815
Contact Person	Dave Croniser Phone: 425.732.2814 ext 303 Fax: 425.732.2815
Common Name	PhysioSonics, Inc. Transcranial Doppler Ultrasound System with two 1.85 MHz Ultrasound Transducer
Proprietary Name	Presto 1000 System; CPA 1875 Transducer
Classification Name, Regulatory Class	Ultrasonic Pulsed Doppler System; Diagnostic Ultrasound Transducer
Federal Regulation Number	21 CFR 892.1550; 21 CFR 892.1570
Product Code	IYN, ITX
Class	Regulatory Class II
Predicate Device:	Spencer Technologies, Inc., K002533 TCD 100 M, Transcranial Doppler Ultrasound System, CFR 892.1550, Product Code: IYN Transducer PWD13, Diagnostic Ultrasound Transducer; CFR. 892.1570, Product Code: ITX
Performance Standards	None Voluntary standards: ISO 10993-5, ISO 10993-10
Special Controls	None

Device Description

The Presto 1000 is a color/PW transcranial Doppler (TCD) ultrasound monitor incorporating two permanently connected two-dimensional phased array transducers, to be used in a headset, for long term bilateral monitoring of blood flow in the M1 segment of the middle cerebral artery (MCA), through the temporal windows. Transducers are intended to be used with single use acoustic couples couplers, which increase patient comfort and improve mechanical compliance to maintain acoustic coupling during long term monitoring. Transducers may only be mounted to the headset when fitted with this acoustic coupler.

Technology

The Presto 1000 is substantially equivalent to currently marketed pulsed Doppler ultrasound systems and transducers used for TCD monitoring. The system generates voltage pulses which are converted in the transducer to acoustic pressure pulses, which are then transmitted through body tissues. Echoes from moving red blood cells are received by the transducer, and converted back into electrical signals which are processed by the system into Doppler shift frequencies corresponding to blood flow velocities. As a dedicated blood flow monitor, The Presto 1000 analyzes these Doppler signals for blood flow metrics, which it displays and logs for later review.

Indications for Use

The Presto 1000 transcranial Doppler ultrasound system is intended for use in the ICU and surgical suite as an ultrasound fluid flow analysis system for the monitoring of middle cerebral artery blood velocities. Vessels intended for monitoring are solely the M1 segments of the middle cerebral arteries via the temporal windows on the left and right sides of the head.

The Presto 1000 calculates cerebrovascular flow index values to identify the presence of hemodynamically significant deviations from normal values. It records changes in these indices over time for later review, displays trends in user selected flow indices, and generates alerts when user selected indices exceed user defined levels, based on physician requirements and patient needs.

The device is not intended to replace other means of evaluating vital patient physiological processes, such as pulse oximetry, electroencephalography or electrocardiography, is not intended to be used in fetal applications, and is not intended to be used in the sterile field.

For Prescription Use Only (Part 21 CFR 801 Subpart D)

Determination of Substantial Equivalence:

1) Comparison to Predicate Device- Technological Characteristics

The Presto 1000 and its transducers are substantially equivalent to its currently marketed predicate device, the Spencer TCD 100M pulsed Doppler ultrasound system and transducers

(K002533) with regard to intended use, modes, clinical measurements, acoustical power output, head fixation devices, safety and effectiveness.

- Both are transcranial Doppler ultrasound systems used for fluid flow analysis
- Both systems monitor the cerebral artery via the temporal windows
- Both systems employ two transducers which are attached via a headset for cephalic monitoring
- Both systems are indicated for adult cephalic use
- Both systems use substantially equivalent operating modes
- Both systems measure equivalent hemodynamic indices.
- Both systems have equivalent monitoring functions.
- Both systems are track 1 devices
- Both systems are manufactured with materials that have been evaluated and found to be safe for the intended use of the device
- Both system have been found to be manufactured to meet applicable physical, mechanical, and electrical safety requirements

Both systems are transcranial Doppler ultrasound flow systems, with monitoring functions. Both systems monitor the cerebral arteries via the temporal windows, with the Presto 1000 dedicated to monitoring the M1 segments, while the TCD 100M additionally examines the anterior and posterior cerebral arteries via the temporal windows, the vertebral and basal arteries via the foramen magnum, and the ophthalmic and intracranial internal carotid arteries via the eye.

Intended uses, modes, clinical measurements, acoustical power output and head fixation devices for the Presto 1000 are equivalent to their TCD 100M monitoring counterparts, and both systems have equivalent performance in measurement of blood flow velocity, as evaluated on Doppler flow phantoms and provide the same clinical indices. The TCD 100M includes additional clinical measurements for emboli counts and resistivity index.

Even though the systems are substantially equivalent with respect to their monitoring functions, the underlying technology implementations are different. Both systems have equivalent modes and use pulsed wave Doppler (PWD), but the Presto 1000 uses a color flow mode while the TCD 100M uses color M mode for location of the vessel of interest. The Presto has a phased array which allows electronic steering and focal adjustment of the acoustic field while the Spencer has a single element transducer with fixed a fixed focal zone. Presto's multi-channel front end exploits the phased array functionality for location and tracking of peak flow within the MCA. Presto's graphical user interface uses this increased functionality of the phased array to provide real-time graphical feedback to guide the user through a structured process to locate the MCA via the temporal windows. The TCD 100M single element array requires manual manipulation for this location and tracking

2) Summary of Non-Clinical Testing Submitted, Referenced, or Relied on in the Submission

The device has been evaluated for acoustic output, biocompatibility, and accuracy, as well as thermal, electrical, electromagnetic, and mechanical safety. Non-clinical testing was conducted to support thermal, mechanical, electromagnetic, and mechanical safety per the FDA *Guidance Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers,* issued September 2008 using applicable sections of the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 (General)
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, Edition 3: 20007 -03 (General)
- IEC 60601-2-37, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, Edition 2.0: 2007 – 08 (Radiology)
- NEMA UD2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3 (Radiology)
- NEMA UD3-2004, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (Radiology)
- AAMI/ANSI/ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity (Biocompatibility)
- AAMI/ANSI/ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (Biocompatibility)

Quality system measures applied to the development of the system included risk analysis, requirement reviews, design reviews, verification and validation, performance testing, and safety testing. Patient contact materials have been shown to be biocompatible. Cleaning and disinfection instructions are provided for the user based on testing to confirm material compatibility.

3) Nonclinical Performance Testing

Nonclinical performance testing of the Presto 1000 evaluated the fundamental accuracy of measured flow velocity using calibrated string phantoms and calibrated volume flow phantoms with a blood mimicking fluid to evaluate the full two-way electroacoustic signal chain. The calculations used to derive secondary flow indices are additionally verified with simulated and electronic data, which allows evaluation to higher accuracy than the reported numbers determined from acoustic measurements.

Testing followed the recommendations of the 2002 2nd edition of the AIUM *Performance Criteria and Measurements for Doppler Ultrasound Devices*, and the September, 2008 FDA

Guidance Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.

Results were compared with similar measurements performed with the Spencer TCD 100M predicate system, and found to be identical within experimental uncertainties. Additional testing verified the Presto 1000's use of phased array technology to locate the peak Doppler signal in the region of interest, and evaluated Doppler sensitivity; both were found appropriate to the intended use.

4) Clinical Testing

The Presto 1000 did not require clinical testing to show substantial equivalence to its predicate device in safety and effectiveness.

General Safety Considerations- Acoustic Output

Acoustic output testing of the Presto 1000 was performed in accordance with AIUM/NEMA's Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, NEMA UD2-2004, Rev. 3, and AIUM/NEMA's Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, NEMA UD3-2004, Rev. 2, as applicable. Acoustic output is reported under Track 1, with global maximum values as discussed below.

Presto 1000 operation is designed to conservatively manage acoustic output during long term monitoring. Each of the two Presto 1000 operating modes uses a single fixed transmit focus and power level, selected to maximize clinical performance in that mode while maintaining a safe level of acoustic output, consistent with ALARA. Global Maximum Cranial Thermal Index (TIC) of 2.6 in Locating mode / 2.3 in Monitoring mode, and Mechanical Index (MI) of 1.0 are consistent with the monitoring function of the predicate device. Maximum Monitoring intensity of 420 mW/cm^2 exceeds the preamendment cephalic limit of 94 mW/cm^2, consistent with the predicate device and other modern TCD systems.

Time average acoustic exposure is reduced by a factor of two in bilateral monitoring, as the system alternates from side to side at user selected intervals. The user may further reduce the time average acoustic output by an additional factor of two by selecting a 50 percent duty cycle of two minutes on and two minutes off, which is the default mode of system operation unless otherwise specified.

The Presto 1000's Track 1 acoustic output summary is provided below; note that these are worst case values, and do not include the time-average reductions in acoustic output discussed above, which will reduce spectral Doppler values of Ispta.3 and TIC by a factor of two for bilateral monitoring or 50% duty cycle operation, or by a factor of four for bilateral monitoring and a 50% duty cycle.

Application: Adult Transcranial Doppler	**System: Presto 1000**	**Transducer: CPA 1875**	
Operating Mode	**MI**	**$I_{SPTA.3}$ (mW/cm^2)**	**TIC**
Color Doppler Non-Autoscanning	1.0	90	2.6
Spectral Doppler Non-Autoscanning	0.6	420	2.3

During system start up the operator is required to acknowledge a caution against using the Presto 1000 for scanning through the eye, burr holes, fontanelles or foramen magnum.

Software

The Presto 1000 uses custom software written in C++ and operates under the Windows 7 operating system; commercial libraries are used to provide signal processing and graphics functions.

Conclusion

The Presto 1000 is a color/PW Doppler ultrasound system optimized for the single application of bilateral TCD monitoring of blood flow in the M1 segment of the MCA, through the left and right temporal windows. It includes two permanently connected two dimensional phased array transducers of the same design, which mount to a headset and employ single use acoustic couplers to facilitate long term monitoring. This comprises a Track 1 device with acoustic intensity exceeding the cephalic limit. Global maximum TIC is 2.6 in Color Doppler, used for short durations to locate the MCA, and 2.3 in Spectral Doppler, used for blood flow monitoring; these values are reduced by factors of two or four in bilateral monitoring or/and operation with a 50% duty cycle.

The Presto 1000 does not embody a new insonation mode, but does provide a new presentation of conventional color and pulsed Doppler information which is substantially equivalent to methods already performed in the predicate device and is used as an aid to the operator.

The documentation provided demonstrates that:

1) The system and transducers are substantially equivalent to the predicate devices
2) There are no new questions of safety and effectiveness concerning the Presto 1000 ultrasound system and transducers
3) The ultrasound device has been evaluated and has been demonstrated to be at least as safe and effective as the cited predicate device.

Accordingly the Presto 1000 is believed to be substantially equivalent to a predicate device of the same type which is lawfully distributed in interstate commerce in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 13, 2012

Physiosonics, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K123565
Trade/Device Name: Presto 1000 Transcranial Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN and ITX
Dated: November 19, 2012
Received: November 20, 2012

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 Presto 1000 Transcranial Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

CPA 1875

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 Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of *In Vitro* Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

1.7 Indications For Use

The Presto 1000 transcranial Doppler ultrasound system is intended for use in the ICU and surgical suite as an ultrasound fluid flow analysis system for the monitoring of middle cerebral artery blood velocities. Vessels intended for monitoring are solely the M1 segments of the middle cerebral arteries via the temporal windows on the left and right sides of the head.

The Presto 1000 calculates cerebrovascular flow index values to identify the presence of hemodynamically significant deviations from normal values. It records changes in these indices over time for later review, displays trends in user selected flow indices, and generates alerts when user selected indices exceed user defined levels, based on physician requirements and patient needs.

The device is not intended to replace other means of evaluating vital patient physiological processes, such as pulse oximetry, electroencephalography or electrocardiography, is not intended to be used in fetal applications, and is not intended to be used in the sterile field.

Prescription Use ___X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use____ ____ (Part 21 CFR 801 Subpart C)

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

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

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

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123565

Presto 1000 Ultrasound Indications for Use Form

System: Presto 1000

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			N		N		
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

ADDITIONAL COMMENTS: The primary mode of operation is using the Doppler information to track trends from standard well established data calculations

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocityt Imaging

Transducer Indications for Use Form

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K123505

Transducer: CPA 1875

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic			N		N		
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)							

ADDITIONAL COMMENTS: The primary mode of operation is using the Doppler information to track trends from standard well established data calculations

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

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging510(k) Summary

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123565