5. 510(K) SUMMARY

K092204

A. Submitter

Spencer Technologies
701 16th Avenue
Seattle, WA 98122 USA
206-329-7220

B. Establishment Registration Number: 3033518

OCT - 8 2009

C. Contact

Name Tony Williams
Title VP Quality Assurance/Regulatory Affairs
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D. Submission Date: 16 July 2009

E. Trademark and Common Name

Spencer Technologies PMD Viewer

F. Classification of the device

Classification Name	Picture Archival and Communications System
Classification Panel	Radiology
CFR Number	21 CFR 892.2050
Device Class	Class II
Product Code	LLZ

G. Predicate Device

The PMD Viewer, addressed in this premarket notification, is substantially equivalent to the following commercially available devices:

Manufacturer	Trade Name	510(k) No	Product Code
Acuson Corporation	CSV12 Software Viewer	K022896	90 LLZ
Spencer Technologies	TCD 100M/PMD150 Diagnostic Ultrasound System	K002533	90 IYN

Note: In this document we refer to the Acuson Viewer as the "predicate device", and to the PMD Viewer as the "predicate (parent) device".

H. Device Description

This device is a software-only version of the Spencer Technologies digital Transcranial Doppler ultrasound system, the TCD100M/PMD150, and is described as the PMD Viewer.

The modification of the TCD100M/PMD150 implemented in the PMD Viewer provides physicians and technologists with the same data viewing, playback, and report generation features of the TCD100M/PMD150 off-line on a standard PC utilizing Windows XP SP2 or VISTA. All software features can be controlled with a standard keyboard and wheel mouse. Because it can read the proprietary binary file formats of the predicate (parent) device, the TCD100M/PMD150, the PMD Viewer displays images without any compression, duplicating the original quality of the images on the TCD100M/PMD150.

I. Intended Use

PMD Viewer is intended to provide the same data viewing, playback, and report generation features of its predicate (parent) device, TCD100M/PMD150, Doppler ultrasound studies, off-line on a standard PC. The data consists of previously acquired information on cerebral arterial blood flow velocity measurements and the occurrence of micro-embolic signals in the cerebral arterial blood flow. PMD Viewer operates exclusively as a stand-alone software product on a standard PC. PMD Viewer is intended for use by a technologist or physician trained in the use of Doppler ultrasound. PMD Viewer is NOT intended to replace any means of evaluating vital patient physiological processes. No new intended uses are claimed.

J. Technological Characteristics and Substantial Equivalence

PMD Viewer is a medical image device that is used with computer hardware in a picture archiving and communications system user environment. It has the same intended use and technical characteristics as the predicate device, the Acuson Corporation CSV12 Software Viewer, listed above. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention, interprets the images and information being displayed and printed.

PMD Viewer utilizes commercially available computer platforms and operating systems (Microsoft Windows XP/Vista) as does the predicate CSV12 Software Viewer. PMD Viewer does not produce any original medical images. All functions for the review of the PMD device files are the same as reviewing the files on the predicate (parent) device, TCD100M/PMD150, with respect to intended use and indications for use, principles of operation, and technological characteristics and design. It is comparable in key safety and effectiveness features. Studies may be transmitted in DICOM or native TCD100M/PMD150 format, to an integrated magneto-optical drive, or over a network.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Tony Williams
VP Quality Assurance/Regulatory Affairs
Spentech, Inc. Doing Business as Spencer Technologies
701 16th Avenue
SEATTLE WA 98122

OCT – 8 2009

Re: K092204
Trade/Device Name: PMD Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 16, 2009
Received: July 22, 2009

Dear Mr. Williams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

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.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATION FOR USE

510(k) Number (if known): K092204

Device Name: *PMD Viewer*

Indications for Use:

The PMD Viewer Software is intended to provide off-line data viewing, playback, and report generation features of transcranial TCD100M/PMD150 Doppler ultrasound studies on a PC. PMD Viewer may only be operated independently, as a software-only product. PMD Viewer is intended for use by a technologist or physician trained in the use of Doppler ultrasound. PMD Viewer is NOT intended to replace any means of evaluating vital patient physiological processes. No new intended uses are claimed.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092204