K121617

diacoustic
MEDICAL DEVICES (PTY) LTD

JUL 27 2012

510(k) Summary

807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	Diacoustic Medical Devices (Pty) Ltd.
Company Address:	19 Quantum Street Techno Park Stellenbosch 7600 South Africa
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Contact Person:	May 22, 2012
Summary Preparation Date:	

DEVICE NAME **807.92(a)(2)**

Trade Name:	Sensi Cardiac Diagnostic Heart Murmur Software
Common/Usual Name	Electronic Stethoscope/Heart Sounds Analyzer
Classification Name	Electronic Stethoscope; Phonocardiograph
Regulation Number	21 CFR 870.1875, 870.2390
Product Code	DQD, DQC
Device Class	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k)*
Zargis Medical Corp	Zargis Acoustic Cardioscan	K083309
Stethographics Inc.	Stethographics Heart STG System	K052283
Diacoustic Medical Devices	Sensi Cardiac Diagnostic Heart Murmur Software	K110704

DEVICE DESCRIPTION **807.92(a)(4)**

The Sensi Diagnostic Heart Murmur Software is a decision support device intended to acquire, record, and anlyze heart sounds. It is used to distinguish between normal/ physiological and pathological heart murmurs by recording the acoustic signal of the heart by means of an electronic stethoscope.

The complete system is a software package comprising Sensi Diagnostic Heart Murmur Software that runs on a computer with Windows operating system, instructions for use and

the electronic stethoscope that captures the acoustic heart signals. The user must provide a compatible electronic stethoscope.

DEVICE INDICATIONS FOR USE **807.92(a)(5)**

Sensi is a decision support software package intended to assist medical examiners in heart auscultation.

The Sensi system consists of the following components:

1. The Sensi Diagnostic Heart Murmur Software program running on a personal computer (PC) with interfaces to:
   - a compatible electronic stethoscope
   - A database with patient and health worker information
   - Functions to record, display, analyze, save and playback heart sounds.
2. A compatible electronic stethoscope with characteristics
   - Recording Frequency Range: 20 Hz to 10,000 Hz
   - Sampling Frequency: > 4,000 Hz
   - Data Recording: Standard .wav files at resolution of 16bit, mono
   - Recording Time: minimum 10 sec, maximum 30 sec
   - Acoustic Sensors: Electronic stethoscope; compatible models include: ThinkLabs Medical ds32a+, Meditron Master Elite, RNK PCP/PC Stethoscope.
   - Number of Sensors: 1

The Sensi Diagnostic Heart Murmur Software distinguishes between normal/ physiological and pathological heart murmurs by analyzing the acoustic heart signals captured with an electronic stethoscope. The device will record the acoustic sound of the heart at the four main auscultation positions.The acoustic heart signal is analyzed to identify heart sounds that may be present, identified sounds include S1, S2 and suspected murmurs.

COMPARISON OF TECHNICAL CHARACTERISTICS **807.92(a)(6)**

The Sensi software device features were directly compared with the FDA cleared Sensi, Zargis Acoustic Cardioscan and Stethographics Heart STG System.

Synopsis of the comparison analysis:

- All three software systems uses equivalent computer platforms.

- Both Sensi and Stethographics uses equivalent accessories, electronic stethoscope. The acoustic performance between the specified electronic stethoscopes are equivalent.
- Both Sensi and Cardioscan uses equivalent signal processing algorithms by analyzing only the recorded acoustic heart signal at the four main recording locations. The new Sensi software's classifier and feature extraction algorithm are identical to the previous FDA cleared Sensi software.
- Patient information and signal display handling are in all three cases equivalent.
- Sensi and Cardioscan's clinical performances are equivalent.
- The new Sensi software's graphical user interface is nearly identical to the previous FDA cleared Sensi software.

After analyzing bench test and user testing data, it is the conclusion of Diacoustic Medical that the Sensi device consisting of the Sensi Diagnostic Heart Murmur Software and compatible electronic stethoscopes is as safe and effective as the predicate device and raises no new issues of safety and effectiveness.

SAFETY AND EFFECTIVENESS **807.92(b)**

A comprehensive list of verification and validation testing was performed in accordance to Diacoustic's Design Control procedures.

Software validation was performed for all aspects of the Sensi System and Software. The graphical user interface and usability were compared to the predicate devices.

Validation of the Sensi was performed to ensure that the Sensi system consistently fulfills its intended use and the needs of the user. Software validation was performed to insure the performance of the software algorithm

Study Type	Results
Feasibility & Usability Study	Usability validation was performed within real life clinical settings by intended users. On average all users scored the usability of the Sensi Software more than 4 out of 5.
Comparative Study between the FDA approved Zargis and Sensi V1 systems and the Sensi V2	Sensi V1 achieves overall accuracy of 70.8%. Cardioscan achieves an accuracy of 67.9% Sensi V2 achieves overall accuracy 69.7%
Design verification of a CAA algorithm	Specificity of 95% and sensitivity of 84%
Comparison of the Sensi V2 software program's graphical user interface and usability to that of the FDA approved Sensi V1	The Sensi V1 and Sensi V2 software packages uses the same tested and trialed graphical user interface. Functional and graphical differences are compared.
Validate algorithms used to distinguish between functional and pathological heart murmurs in the pediatric population.	1568 heart sounds were accepted to meet the criteria of good quality and match the recorded pathological condition

Comparing Sensi V1 and Sensi V2 in a clinical screening environment.	43 patients with cleft lips and palates were screened with Sensi V1 and the recorded database was used to validate Sensi V2.
Stethoscope Comparison Study	A study was conducted to verify the technical equivalence between the stethoscopes specified.

CONCLUSION

Based upon the indications for use, technological characteristics and safety and performance testing, it is the conclusion of Diacoustic Medical that the Sensi device consisting of the Sensi Diagnostic Heart Murmur Software and a compatible electronic stethoscope is as safe and effective as the predicate devices and raises no new issues of safety and effectiveness.

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

JUL 27 2012

Diacoustic Medical Devices
C/O E.J.Smith
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K121617
Trade/Device Name: SensiCardiac
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: May 24, 2012
Received: June 1, 2012

Dear Mr. Smith:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): _____

Device Name: SensiCardiac

Indications for Use:

The SensiCardiac is an electronic auscultatory device, intended to provide support to the physician in the evaluation of patients' heart sounds. The product acquires and records the acoustic signals of the heart and analyzes these signals. The analysis procedure will identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs. The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.

The interpretations of heart sounds offered by the SensiCardiac are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

Prescription Use ___✓____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K121617