510(k) Summary

807.92(c)

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

Company Name: Diacoustic Medical Devices (Pty) Ltd.
Company Address: Electron Street
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South Africa
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Contact Person: Matthys Cronje
Summary Preparation Date: March 13, 2013

SEP 0 4 2013

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

Trade Name: **SensiCardiac Mobi** Diagnostic Heart Murmur Application
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
Reviewing Panel: Cardiology

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

Legally Marketed Equivalent Device

Company	*Product*	*510(k)*
Diacoustic Medical Devices	Sensi Cardiac Diagnostic Heart Murmur Software	K121617

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

The **SensiCardiac Mobi** Diagnostic Heart Murmur Application 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 application comprising Sensi Diagnostic Heart Murmur Algorithm that runs on a hosted server environment with Linux operating system, a hand held device to capture patient data, instructions for use and the electronic stethoscope that captures the acoustic heart signals. The user must provide a compatible electronic stethoscope.

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

The **SensiCardiac Mobi** system consists of the following components:

1. The Sensi Diagnostic Heart Murmur Algorithm running within a hosted environment with TCP/IP interfaces to:
   - a hand held mobile device (iPhone 4S or later)
   - A database with patient and health worker information
2. A hand held mobile device (iPhone 4S or later) with the following uses:
   - electronic transfer of the medical device data (TCP/IP interface)
   - the electronic interfacing and conversion of the electronic stethoscope audio signal.
   - The electronic display of medical device data.
   - Capturing of basic patient information.
3. 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
   - Electronic stethoscope; compatible model: ThinkLabs Medical ds32a+
   - Number of Sensors: 1

The Sensi Diagnostic Heart Murmur Algorithm 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.

The Sensi Diagnostic Heart Murmur Algorithm or the application running on the hand held mobile device does not control the medical device (electronic stethoscope) or actively monitoring the patient.

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

The SensiCardiac Mobi 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 Mobi are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

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

The **SensiCardiac Mobi** software device features were directly compared with the FDA cleared Sensi Cardiac Diagnostic Heart Murmur Software. Both systems use the exact same Diagnostic Heart Murmur Algorithm and electronic stethoscope to capture the heart sounds. The user interface was adapted to function on the latest mobile hand held devices and the algorithm implemented as a hosted service.

Synopsis of the comparison analysis:

- Both systems use the exact same (identical) Diagnostic Heart Murmur Algorithm for analyzing the heart sounds. No modifications were made to the FDA cleared Sensi Cardiac Diagnostic Heart Murmur Software's algorithm and used as is within **SensiCardiac Mobi**.
- Both systems use equivalent computer platforms to execute the Diagnostic Heart Murmur Algorithm. No computational or control functions were implemented on the mobile hand held device.
- Both systems interfaces to the same electronic stethoscope (ThinkLabs Medical ds32a+).
- Equivalent patient information is captured on both platforms.
- The clinical performance of both systems is equivalent.
- An equivalent workflow and graphical user interface were implemented on **SensiCardiac Mobi**, as used within the FDA cleared
- The new **SensiCardiac Mobi** software's graphical user interface is nearly identical to the previous FDA cleared Sensi Cardiac Diagnostic Heart Murmur Software.

After analyzing bench test and user testing data, it is the conclusion of Diacoustic Medical that the **SensiCardiac Mobi** 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 **SensiCardiac Mobi** system and software. The graphical user interface and usability were compared to the predicate devices.

Validation of the **SensiCardiac Mobi** was performed to ensure that the **SensiCardiac Mobi** system consistently fulfills its intended use and the needs of the user. Software validation was performed to insure the performance of the software algorithm is identical to that of the Sensi Cardiac Diagnostic Heart Murmur Software.

Study Title	Results
SensiCardiac Mobi: Verification Study and Comparison	FDA cleared **SensiCardiac** and **SensiCardiac Mobi** achieves the same results on the same data set. The two systems' diagnostic features are therefore equivalent.
SensiCardiac Mobi: Graphical User Interface Comparison	The graphical user interface of **SensiCardiac Mobi** compares favorably to **SensiCardiac** with similarities between all the major display and interface functions. **SensiCardiac** was used as baseline for the development; usability improved.
SensiCardiac Mobi: Acoustic Performance Study	Results indicated that the iPhone 4S and 5 devices running iOS 6 are more than adequate for this application.
SensiCardiac Mobi: Usability Verification	**SensiCardiac Mobi** scored high on usability and is seen as a major improvement on the PC version of this application.
Development of a Pediatric Cardiac Computer Aided Auscultation Decision Support System	Specificity of 94% and sensitivity of 84% (relative to golden standard - echo)
Qualitative Computer Aided Auscultation Study by Intended Users	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.
APCA Clinical Report	1568 heart sounds were accepted to meet the criteria of good quality and match the recorded pathological condition (all patients were echoed – golden standard)

CONCLUSION 807.92(b)(3)

Based upon the indications for use, technological characteristics and safety and performance testing, it is the conclusion of Diacoustic Medical that the **SensiCardiac Mobi** device consisting of the Sensi Diagnostic Heart Murmur Algorithm, a mobile hand held device and a compatible electronic stethoscope is as safe and effective as the predicate device 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 Center – WO66-G609
Silver Spring, MD 20993-0002

September 4, 2013

Diacoustic Medical Devices (Pty) Ltd.
c/o Ms. Yolanda Smith
Consultant
Smith Associates
1468 Harwell Ave
Crofton, MD 21114

Re: K131044
Trade/Device Name: Diacoustic Medical Devices (PTY) Ltd
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DQC
Dated: July 15, 2013
Received: July 16, 2013

Dear Ms. 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 contact 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. 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,

Owen P. Faris -S

for

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

Enclosure

Indications for Use

510(k) Number (if known): K131044

Device Name: SensiCardiac Mobi

Indications for Use:

The SensiCardiac Mobi 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 Mobi are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owon P. Faris -S
Date: 2013.09.04 10:18:27 -04'00'