510 (k) Summary

807.92(c)

JUN 2 4 2013

SPONSOR	**807.92(a)(1)**
Company Name:	Rijuven Corporation
Company Address:	624 Whispering Pines Drive Pittsburgh PA, 15238
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Contact Person	Evens Augustin
Summary Preparation Date:	March 2, 2013

DEVICE NAME	**807.92(a)(2)**
Trade Name:	CardioSleeve
Common/Usual Name:	Electronic Stethoscope / Heart Sound 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) #*
Diacoustic Medical Devices (Pty) Ltd	Sensi with Diagnostic Heart Murmur Software	K110704

DEVICE DESCRIPTION 807.92(a)(4)

The CardioSleeve with Diagnostic Heart Murmur Application, (application identical to the FDA cleared Sensi with Diagnostic Heart Murmur Software-K110704), is a decision support device intended to acquire, record, and analyze heart sounds. It is used to distinguish between normal and pathological heart murmurs by recording the acoustic signal of the heart and the ECG signal simultaneously and analyzing these signals, and to acquire, record and display 3 Lead ECG signals for diagnostic support.

The complete system comprises of: a) Diagnostic Heart Murmur Algorithm (algorithm identical to the FDA cleared Diagnostic Heart Murmur Algorithm in K110704), that runs on a hosted server environment with Linux operating system, b) a mobile device software application that captures patient data, displays patient data and instructions for use and c) a stethoscope front-end recorder device with integrated ECG to acquire the acoustic and electrical heart signals. The CardioSleeve Front-end recorder device will interface via Bluetooth with the clinician's hand held mobile device.

DEVICE INDICATIONS FOR USE 807.92(a)(5)

The CardioSleeve System consisting of the CardioSleeve Front-End stethoscope with integrated ECG device, mobile heart sound and ECG recording application and the remote diagnostic heart murmur software is a decision support device intended to be used on a single patient to assist the qualified clinician in analyzing cardiac sounds and electrical signals for the identification and classification including of suspected murmurs. It is used to distinguish between normal/physiological and pathological heart murmurs by recording the acoustic signal of the heart and the ECG signal simultaneously and analyzing these signals. The acoustic heart signal is analyzed to identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs.

CardioSleeve indicates whether or not a recorded heart sound contains a suspected heart murmur. The device must be used in a clinical setting by trained personnel with the prescribed accessories and all relevant patient information must be taken into consideration before a diagnosis is made.

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

CardioSleeve is not intended to be a diagnostic device. It does not supersede the judgment of the clinician. The device is intended to aid the physician in the evaluation of heart sounds. The clinicians are responsible for reviewing and interpreting the results, along with the auscultatory findings and medical history, when making a referral decision.

Caution: Federal (USA) law restricts this device to sale by or on the order of a clinician

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

The CardioSleeve device features were directly compared with the FDA cleared Sensi with Diagnostic Heart Murmur Software, WelchAllyn Master Elite Stethoscope and the WelchAllyn Meditron Analyzer (K110704).

Synopsis of the comparison analysis:

- Intended Use:

  CardioSleeve and Sensi with Diagnostic Heart Murmur Software do have an equivalent intended use.

- Indications for Use:

  CardioSleeve and Sensi with Diagnostic Heart Murmur Software do have identical indications for use.

- Composition

  CardioSleeve and Sensi with Diagnostic Heart Murmur Software compromises equivalent functions system composition.

- Physical Properties

  CardioSleeve with Front-end unit and Diagnostic Heart Murmur Software, and Sensi with Diagnostic Heart Murmur Software, the WelchAllyn Master Elite Stethoscope and the WelchAllyn Meditron Analyzer share equivalent physical characteristics (K110704).

- Technology Characteristics

  CardioSleeve consists of a front-end recorder device with a Bluetooth interface connected to a standard acoustic stethoscope recording both the acoustic heart sound and/or ECG signal. The Sensi consists of an electronic stethoscope and ECG recorder connecting to a PC by means of a USB interface for recording of acoustical body sounds.

  CardioSleeve and Sensi with Diagnostic Heart Murmur Software are using identical heart murmur analysis algorithm.

  CardioSleeve and Sensi with Diagnostic Heart Murmur Software are using equivalent user interface properties.

SAFETY AND EFFECTIVENESS 807.92(b)

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

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

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

1	Biocompatibility Testing	CardioSleeve material presented no issues of biocompatibility
2	Electrical Safety Testing	The CardioSleeve meets the requirements of IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007).
3	Feasibility & Usability Study	Intended users performed usability validation within real life clinical settings. On average all users scored the usability of the CardioSleeve Software more than 4 out of 5.
4	Comparative study between FDA approved CardioSleeve and Sensi system	CardioSleeve and Sensi achieve comparable accuracy of 70.8%
5	Design verification of a CAA algorithm	Specificity of 94% and Sensitivity of 91%
6	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 conditions
7	Verification of the acoustic performance of the CardioSleeve front-end	The CardioSleeve Front-End perform favorably, in responding to heart sound frequency of 20hz to 500hz

CONCLUSION **807.92(b)(3)**

Based upon the indications for use, technology characteristics and safety and performance testing, it is the conclusion of Rijuven that the CardioSleeve device consisting of the CardioSleeve Front-End stethoscope and ECG device, mobile heart sound recording application and the remote diagnostic heart murmur software 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 Center - WO66-G609
Silver Spring, MD 20993-002

June 24, 2013

Rijuven Corp
Mr. E.J. Smith
Regulatory Consultant
1468 Harwell Ave.
Crofton, MD 21114 US

Re: K131287
Trade/Device Name: Cardiosleeve
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope / Heart Sound Analyzer
Regulatory Class: Class II
Product Code: DQD, DQC
Dated: May 9, 2013
Received: May 9, 2013

Dear Mr. E.J. 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.htmfor 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 D. Zuckerman -S

Bram D. Zuckerman, Ph.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: CardioSleeve

Indications For Use:

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CardioSleeve indicates whether or not a recorded heart sound contains a suspected heart murmur. The device must be used in a clinical setting by trained personnel with the prescribed accessories and all relevant patient information must be taken into consideration before a diagnosis is made.

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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)

Bram D. Zuckerman -S
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