K052283

Stethographics, Heart STG System 510(k) Summary

Company:

Stethographics, Inc
1153 Centre Street
Boston, MA

DEC 2 3 2005

Owner:

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Contact:

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Stethographics, Inc
1153 Centre Street
Boston, MA

Date Prepared:

August 17, 2005

Name of Device:

Stethographics Heart STG System

Common Name of Device:

Electronic Stethoscope

Classification Name:

Heart STG System
21 CFR 870.1870

Predicate Devices:

The Stethographics Heart STG System is substantially equivalent to the Zargis' Acoustic Cardioscan (#K031517).

Stethographics Inc. Heart STG

Intended Use:

The Stethographics Heart STG is software intended to provide support to the physician in the evaluation of heart sounds in patients.

The product will acquire and record the acoustic signals of the heart and analyze these signals. The analysis procedure will identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected systolic murmurs.

The device is indicated for use in the clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It in not intended as a sole means of diagnosis.

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

Device Description:

The Heart STG is software intended to provide support to medical personnel in the evaluation of heart sounds. The software records and analyzes an acoustic signal of the heart. The analysis procedure aids the healthcare provider by marking S1, S2, and suspected systolic murmurs on the waveform.

As a complete system the Heart STG system consists of an electronic stethoscope and software running on a computer with Windows operating system. The user must provide a compatible electronic stethoscope and a computer.

Technological Characteristics:

The technological characteristics of the new device are compatible to those of the predicate devices.

Performance Data:

Both bench testing and clinical testing were performed to ensure that the device performs as intended. The information supplied in this pre-market notification includes descriptive information about the intended use, operation and technological characteristics.

This information is provided pursuant to the requirements of the Safe Medical Devices Act of 1990 (SMDA).

Device Specification

Recording frequency range	20Hz to 2000Hz
Sampling frequency	8,000 Hz
Data recording	Standard .wav (PCM) files at resolution of 16 Bit, Mono.
Recording time	20 seconds
Acoustic sensor	Electronic stethoscope. Compatible models include Andromed iStethos, Cardionics e-Scope, 3M E-4000.
Number of sensors	1

Heart Sound Analysis STG Performance Data

In order to evaluate the Heart STG with both common heart disorders and more rare disorders, two different sets of cardiac sounds were utilized. The first set of cardiac sounds were obtained by using the Heart STG to record 91 patients that were scheduled for echocardiography assessment (referred to as the STG data set). The second set was created by digitizing all heart sounds provided in the Clinical Auscultation of the Cardiovascular System, by Proctor Harvey and David C. Canfield (referred to as the Proctor Harvey data set). The Proctor Harvey course is considered the gold standard for cardiac auscultation training and covers a broad range of heart disorders (363 sounds total), both common and rare. All sounds were graded by three experienced cardiologists. The sound was considered murmur positive when 2 out of 3 cardiologists agreed on the presence of murmur.

The STG data set included 91 sounds from 91 patients that were scheduled for echocardiography assessment. Average age was 61±17 years (range 23 to 94). The gender distribution in this population was 44% male and 56% female. The patients were asked to hold their breath during the recording. The STG recorded 20 second sounds from each patient. Table 1 compares STG performance to that of the cardiologists. The '+' indicates murmur-positive sounds and '-' indicates murmur-negative sounds.

Table 1. STG compared to 2 out of 3 cardiologists. STG Data Set.

Number of sounds 91	2 out of 3 cardiologists +	2 out of 3 cardiologists -
Heart STG +	23	4
Heart STG -	10	54

The corresponding overall percent agreement = 100%*(23 + 54)/91 = 85%
Agreement of the STG with 2/3 cardiologists-positive = 100%*(23)/(23+10) = 70%
Agreement of the STG with 2/3 cardiologists-negative = 100%*(54)/(54+4) = 93%

The Proctor Harvey data set included 363 sounds from 232 patients. Sixty-three sounds were recorded from children, 300 from adults. The Proctor Harvey data set is representative of great number of common and less common heart pathologies and, consequently, allows us to judge the algorithm's performance in both common and less

common heart conditions. Table 2 compares STG performance to that of the cardiologists.

Table 2. STG compared to 2 out of 3 cardiologists. Proctor Harvey Data Set.

Number of sounds 363	2 out of 3 cardiologists +	2 out of 3 cardiologists -
Heart STG +	227	43
Heart STG -	23	70

The corresponding overall percent agreement = 100%*(227 + 70)/363 = 82%
Agreement of the STG with 2/3 cardiologists-positive = 100%*(227)/(227+23) = 91%
Agreement of the STG with 2/3 cardiologists-negative = 100%*(70)/(70+43) = 62%

The agreement between cardiologists was also calculated, Tables 3 and 4, columns 3 to 8.

Table 3. Agreement between cardiologists. STG Data Set.

	STG compared to 2 out of 3 cardiologists	Cardiologist 1 with cardiologist 2 as a gold standard	Cardiologist 1 with cardiologist 3 as a gold standard	Cardiologist 2 with cardiologist 1 as a gold standard	Cardiologist 2 with cardiologist 3 as a gold standard	Cardiologist 3 with cardiologist 1 as a gold standard	Cardiologist 3 with cardiologist 2 as a gold standard
Agreement with murmur-positive	70	91	100	72	93	67	79
Agreement with murmur-negative	93	79	77	94	89	100	96

Table 4. Agreement between cardiologists. Proctor Harvey Data Set.

	STG compared to 2 out of 3 cardiologists	Cardiologist 1 with cardiologist 2 as a gold standard	Cardiologist 1 with cardiologist 3 as a gold standard	Cardiologist 2 with cardiologist 1 as a gold standard	Cardiologist 2 with cardiologist 3 as a gold standard	Cardiologist 3 with cardiologist 1 as a gold standard	Cardiologist 3 with cardiologist 2 as a gold standard
Agreement with murmur-positive	91	97	97	83	94	82	93
Agreement with	62	61	60	91	86	91	88

murmur-negative							

Thus, the STG agreement with 2/3 cardiologists was found to be comparable to that measured among experienced cardiologists.

Heart Rate (HR) was validated by comparing the HR calculated by the STG to that calculated by 3M Littmann E4000 stethoscope. The correlations between the Heart STG and Littmann E-4000 electronic stethoscope for the STG data set and Proctor Harvey data set are 0.96 and 0.91, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2005

Stethographics, Inc.
c/o Ms. Rozanne Paciej
Director, Regulatory Affairs Quality Assurance
1153 Centre Street
Boston, MA 02130

Re: K052283
Trade Name: Stethographics Heart STG System
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II (two)
Product Code: DQD
Dated: November 14, 2005
Received: November 22, 2005

Dear Ms. Paciej:

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 such 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); 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 Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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): K052283

Device Name: Stethographics Heart STG System

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Bram D. Zuckerman, MD

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052283

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