ACTIVESIGNALTECH.COM

ACTIVE SIGNAL TECHNOLOGIES

MAR 3 1 2011

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Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR Part 807.92 for the Active Signal Noise-Immune *A SCOPE*™ electronic stethoscope.

1. Company making the submission:

2.

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Device Classifications:

Common/ Usual Name	Stethoscope electronic / monitor, Ultrasonic – nonfetal
Trade Name	*A SCOPE*™
Proprietary Name	A SCOPE™
Regulation Number	870.1875 (b)
Product Code	JAF & DQD
Classification Panel	Cardiovascular / Radiology

Expedited Review Of Premarket Submissions for Devices	Yes, from US Army Medical Research & Material Command
Considered confidential (21 CFR 807.950)	Yes
Reviewed By Third Party	NO
Substantial Equivalence (Predicate Devices)	K973336, IMEX Stethodop, K961301, E-Scope and K910462 Pocket DOP 3

3. **Predicate Devices:**

The *A SCOPE*™ stethoscope is substantially equivalent to other electronic and Ultrasound devices in the market such as the IMEX Stethodop (K973336), Pocket DOP 3 (K910462 and E-Scope (K961301).

4. **Intended Use Statement:**

The Active Signal Noise-Immune Stethoscope *Ascope*™ is intended for medical diagnostic purposes only. It may be used for the detection and amplification of acoustic signals generated by physiologic activity of the heart, lungs, bowel, and other internal organs. It can be used on any person undergoing a physical assessment.

1. In the presence of relatively benign ambient noise (e.g., loud accident scenes, ambulances, emergency rooms, civilian Medevac helicopters, etc.) the device is configured as an amplified electronic stethoscope employing a passive piezoelectric sensor. Ingress of ambient sounds is minimized using a passive technique that combines housing mass and specific design of the piezoelectric mechanism to reject external noise.

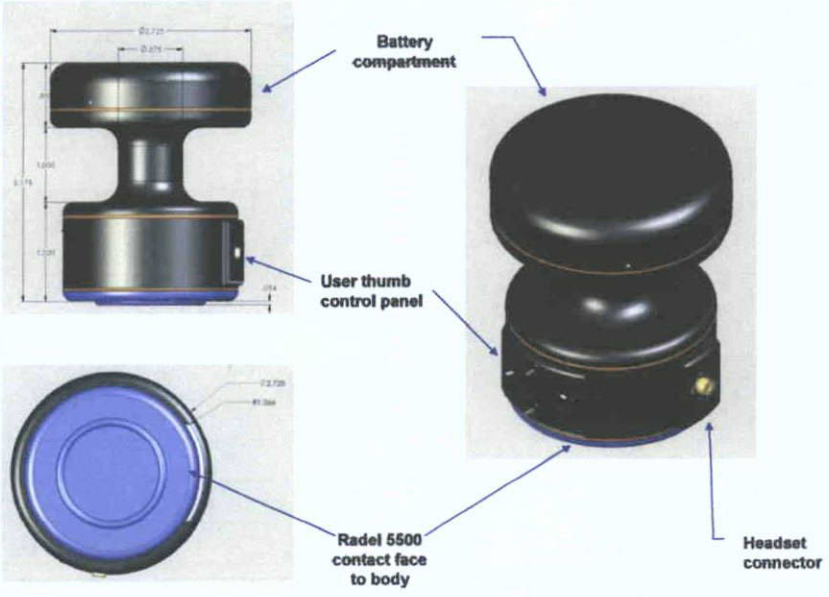
2. When the ambient sound levels exceed the passive sensing limit (e.g., aboard military helicopters, transport aircraft and ships), an active Doppler mode is engaged. This transposes the detection of vital physiologic activity from the

audio frequency range (used by conventional and electronic stethoscopes) to the ultrasound band. Thus the technical challenge of discerning low amplitude physiological signals intermixed with high amplitude noise signals in the same frequency band is circumvented by translating the desired signals to frequencies far removed from the competing ambient noise.

It is NOT intended to be used for diagnosis and treatment by unlicensed, untrained, or unqualified medical persons.

5. **Description of Device:**

BACKGROUND: A stethoscope is one of the few diagnostic tools available to emergency medical personnel far-forward in the battlefield or in the civilian pre-hospital environment. However, the ability to hear subtle physiological sounds (auscultation) and detect life threatening conditions is frequently compromised by competing noises and commotion at the scene of injury or aboard medical transports.



PRINCIPLES OF OPERATION: Active Signal's stethoscope combats noise intrusion through use of two modes of operation depending on the intensity of background noise:

1. In the presence of relatively benign ambient noise (loud accident scenes, ambulances, emergency rooms, civilian Medevac helicopters, etc.) the device is configured as an

amplified electronic stethoscope employing a passive piezoelectric sensor. Noise rejection is imparted by design of the piezoelectric element and mass of the housing.

2. When the ambient sound levels exceed the passive sensing limit, an active Doppler mode is engaged. This transposes the detection of vital physiological sounds from the audio frequency range (used by conventional or electronic stethoscopes) where physiological sounds typically overlap the background noise and hence are swamped out, to ultrasound which puts the measurement into an entirely different frequency band.

DEVICE CONFIGURATION: The top section of the device is the battery compartment, which contains two 1.5V AA-cells. The device is held between the index and middle fingers, with the thumb free to operate a 4-button control panel shown at here. The bottom section contains the stethoscope sensors and signal-processing electronics. For operation as a passive amplified electronic stethoscope (Mode 1, above), a tall column of piezoelectric ceramic material is used as the sensing element contacting the center of the front face. At the top, this column is pressed against the stethoscope's casing. For the active ultrasound-Doppler mode of operation (Mode 2, above), two semicircle-shaped disks, made of piezoelectric material, are embedded in the sensor head, where one functions as a transmitting and the other as a receiving transducer. Details of the mounting geometry, the gap size between the discs and the gap orientation, and also the carrier frequency, determine the width of the sound beam and its penetration depth.

A thumb-operated 4-button control panel allows the device to be turned on (press any mode button), the signal volume to be set (+ and – buttons in the horizontal plane), and the operating mode to be selected.

6. Summary of the technological characteristics of the device compared to predicate devise:

The differences between the Active Signal Noise-Immune

Stethoscope the *A SCOPE™* and the predicate devices are:

a. The *A SCOPE™* combines the continuous wave (CW) Doppler ultrasound technology of IMEX Stethodop (K973336) and the acoustic sensing technology of E-Scope (K961301), into one device.

b. *A SCOPE™* does not have conventional stethoscope ear tips. The *A SCOPE™* utilizes ear buds and light weight electrical cables.

c. The *A SCOPE™* does not claim Doppler blood flow and/or blood pressure capability as does the IMEX Stethodop (K973336). The *A SCOPE™* does claim the ability to detect heart and lung returns in very high noise level environments with Doppler technology.

d. The *A SCOPE™* does not claim capability to monitor fetal position and viability as does the IMEX (Nicolet) Pocket DOP 3 (K910462). The A SCOPE™ does claim the ability to detect movement (activity) in the heart and lungs.

e. The *A SCOPE™* does not have a selectable filter setting as does the Cardionics E-Scope.

f. Unlike all of the predicate devices, the *A SCOPE™* does not have built-in ear pieces or headphones or a speaker. Instead it requires connection to an external output device such as earphones, headphones or a speaker.

Testing:

Testing of the *A SCOPE™* included ISO 60601-X Standards as they apply, bench testing, testing to applicable FDA Guidance Documents, and U.S. Army qualification testing. The *A SCOPE™* has successfully completed all required testing with positive end points.

7. Rx or OTC

The *A SCOPE™* is a Prescription Use device per 21 CFR 807 Subpart D.

8. Conclusions:

Based on testing and comparison to predicate devices, the *A*

SCOPE™ has the same intended use, and is substantially equivalent to the predicated devices. The device performs as intended.

Active Signal Technologies, Inc.

Arthur Cooke
President

Date: 2.4.2011

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

Active Signal Technologies, Inc.
c/o Mr. J. Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071

MAR 31 2011

Re: K103499
Trade/Device Name: A SCOPE™
Regulation Number: 21 CFR 870.1875
Regulation Name: Electronic Stethoscope
Regulatory Class: Class II (two)
Product Codes: DQD, JAF
Dated: February 16, 2011
Received: February 18, 2011

Dear Mr. Knauss:

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,

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 Statement

510(k) Number: K103499

Device Name: **Active Signal Noise Immune Stethoscope**

Indications for Use:

The Active Signal A SCOPE (or noise-immune stethoscope) is intended for medical diagnostic purposes only. It may be used for the detection and amplification of acoustic signals generated by physiologic activity in the body. In the presence of relatively mild ambient noise it is used in Acoustic Mode and functions as a passive electronic stethoscope to receive sounds produced by the heart, lungs, bowel and other internal organs. To retain audibility at higher sound levels it is switched to Doppler Mode where an audible tone is produced by the ultrasound frequency-shift caused by motion of the heart and lungs.

It can be used on any person undergoing a physical assessment. It is not intended to be used for diagnosis and treatment by unlicensed, untrained, or unqualified medical persons.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The Counter Use NO (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K103499

Delphi Consulting Group
Houston, TX 77071

Appendix A

Diagnostic Ultrasound Indications

System: A SCOPE
Transducer: 2 MHz CW

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify) (i)				X			X (ii)
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix
* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

(i) Non-imaging, detection of heart and lung tissue motion
(ii) Tissue Motion Doppler