JUN 9 1999

K990809

CADItec

Medical Instruments

CH-6343 Rotkreuz-Zug, Switzerland
Phone xx41-41-79 80 120
Fax xx41-41-79 80 133

12. SUMMARY OF SAFETY AND EFFECTIVENESS

1 February, 1999

1. SUBMITTER/APPLICANT - COMPANY INFORMATION
Registration #: None
CADItec AG,
EURO 1
Rotkreuz-Zug
Switzerland, CH6343
Phone : xx41-41-79 80 120
Fax : xx41-41-79 80 133
Email : sales@caditec.com
Contact Person: Fridolin Voegeli
Contact Title: President

2. SUBMISSION CORRESPONDENT
Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060
Registration #: 1417592
Phone: (847) 949-5500 x1131
Fax: (847) 949-2643
Contact Name: Christine M. Galea, Submission Correspondent

3. REGULATORY INFORMATION:

DEVICE NAME:	Stethoscope, Electronic
PROPRIETARY NAME:	CADIscope Electronic Stethoscope with Integrated ECG
COMMON NAME:	Electronic Stethoscope
CLASS:	II
PRO CODE:	DQD (870.1875)
PERFORMANCE STANDARDS:	None

4. DEVICE DESCRIPTION: The CADIscope is a patented electronic stethoscope with an integrated graphics display to show the amplified heart sounds as phonocardiograms and show parallel to the heart sounds the ECG in a standard Einthoven Triangle.

5. INTENDED USE: It is intended for use as a diagnostic aid as part of a physical assessment of a patient by health care professionals or other individuals trained to administer emergency first aid or otherwise care for a patient.

It can be used for the amplification of heart, lung, blood vessel, enteral and other body sounds. When the device's integral electrodes are placed on the chest of the patient, it is capable of verifying the existence of cardiac biopotential activity. The quality of the biopotential activity display depends upon user technique and environmental conditions and it is in no way meant to be diagnostic.

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6. SUBSTANTIAL EQUIVALENCE: The CADIscope, with it's sound channel, is substantially equivalent to other electronic stethoscopes on the market. CADIscope claims for it's sound channel, substantial equivalence to the E-Scope Electronic Stethoscope Model 718-7120, K961301 manufactured by Cardionics Inc., 1100 Hercules Ave, Suite 210, Houston, 77058 TX.

   The CADIscope, with it's ECG display, is substantially equivalent to other small portable electrocardiographs on the market. CADIscope claims for it's ECG display, substantial equivalence to the Miniscope MS-3, Electrocardiograph, K954066, manufactured by Schiller AG, Altgasse 68, CH-6340 Baar, Switzerland.

7. COMPARISON TO PREDICATE DEVICE: The **CADIscope is similar to the E-Scope** in that they both are electronic stethoscopes that operate on batteries. Both stethoscopes work by amplifying and filtering the heart sounds and allowing the user of the device to adjust the volume in order to better hear the heart sounds.

   The CADIscope is different than the E-Scope in that it has a visual representation of the heart sounds (or the ECG) and the E-Scope does not. (And therefor the CADIscope contains a microprocessor and the E-Scope does not.)

   The **CADIscope is similar to the Miniscope MS-3** in that they both are battery operated portable monitors with 3 built-in electrodes to pick up the ECG in an Einthoven Triangle (or Tripode). In both devices the microprocessor optimizes the signal's amplitude and displays a 1-lead ECG on a LCD using similar resolution and base-line and noise filtering technology.

   The CADIscope is different than the Miniscope MS-3 in that it does not have memory to store the (two) ECG signal's data over minutes to be played back on the internal LCD or to be transmitted to and analyzed by special ECG analysis programs on special cardiographs or PC's. The Miniscope MS-3 does also offer the possibility to connect an external patient cable with 3 or 5 leads, the CADIscope does not.

		Predicate Devices		**New Device**
	Characteristic	**Cardionics E-Scope Electronic Stethoscope**	**Schiller Miniscope MS-3 Electrocardiograph**	**CADItec CADIscope Electronic Stethoscope**
1	**Intended use**	diagnostic aid, part of physical assessment of patient : amplification of body sounds	diagnostic aid, part of physical assessment of patient : Display of ECG	diagnostic aid, part of physica assessment of patient : amplification of body sounds
2	**Indications**	any time an assessment of a patient's physical condition is required	any time an assessment of a patient's physical condition is required	any time an assessment of a patient's physical condition is required

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		Predicate Devices		New Device
	Characteristic	**Cardionics E-Scope Electronic Stethoscope**	**Schiller Miniscope MS-3 Electrocardiograph**	**CADItec CADIscope Electronic Stethoscope**
3	**Environment**	anywhere	anywhere	anywhere
4	**Personnel requirements**	individuals that have had medical or first aid training with a stethoscope, plus teachers, students	physicians, nurses, or allied health professionals and their students	individuals that have had medical or first aid training with a stethoscope
5	**Sound pickup**	screw-on selectable : - diaphragm flat shape - bell shape	none	bell shape
6	**Microphone**	subminiature back-electret microphone	none	subminiature back-electret microphone
7	**Sound amplification**	electronic, analog amplifier, 0 – 27 dB at 200 Hz, continuos	none	electronic: analog amplifier, 0–35 dB, 16 levels 5 dB each
8	**Sound Operating modes**	bell and diaphragm mode, heart and breast sound filter	none	Organ specific : heart, lungs, and entero filter
9	**Sound Frequency response**	2 filters : heart : 100-240 Hz (-900Hz@ -20dB) breast : 125-350 Hz. (-2000Hz@ -20dB)	none	3 filters : heart: 15-600 Hz. lungs: 300-1500 Hz. Entero: 15-1500 Hz. (@ -20 dB)
10	**Sound speaker**	1 speaker, in control box	none	2 earphones in the ear, reduced noise induction into binaurals
11	**Binaurals**	short metal tubes	none	none
12	**On/Off controls**	On switch Off time controlled by electronics	On switch Off time controlled by electronics	manual On Off time controlled by microprocessor
13	**Mode / filter / sound controls**	mode switch > filters analog potentiometer for volume	none	mode switch > filters + / - switch for volume
14	**Technology**	discrete electronics, integrated op amps	surface mount devices, digital signal processor	surface mount devices, mixed signal processor
15	**Power consumption**	est 100 mW peak est 10 mW normal	est 250 mW	30 mW peak 5 uW sleep mode
16	**Batteries**	1 x 9V, Alkaline, 45 gr in control-box, 150 hours operation = ½ year normal operation	2 x 1.5V, Alkaline, 20 grams 12 hours operation	3 x 1.5V, Alkaline, 30 grams in chestpiece, 160 hours operation = ½ year normal use
17	**Dimensions**	overall length 84 cm total weight 250 grams	77 x 126 x 20 mm total weight 250 grams	cord length 64 cm total weight 170 grams
18	**Display**	none	LCD 64 x 192 pixels, graphics and status display	LCD 64 x 96 pixels, graphics and status display

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		Predicate Devices		New Device
	Characteristic	**Cardionics E-Scope Electronic Stethoscope**	**Schiller Miniscope MS-3 Electrocardiograph**	**CADItec CADIscope Electronic Stethoscope**
19	**Phonocardio-gram visualization of sounds**	no	no	yes, analog sound envelope on built-in display, 4 time-bases, with freeze function
20	**Display of cardiac biopotentials**	no	Built-in three-point electrode or 3 or 5 lead patient cable, display 1 lead, with freeze and playback	swiveling electrodes, forming Einthoven triangle, display time parallel to hearing, with freeze function
21	**Role of micro-processor**	none	switches modes, amplifi-cation, displays status controls	switches modes, amplifi-cation, displays status controls, displays and selects optimum scales
22	**Signal storage**	no	30 min 1 lead ECG	no
23	**Signal trans-mission to other persons or to PC**	- option second headset - option cable for telemedicine over phone	Optional adapter with RS232 and analog output	Optional analog output to hearing aides, second earphone
24	**Infection control**			cleaning and disinfection procedure in Operators' Manual
25	**Materials in: chest contact**	aluminum rings polycarbonate diaphragm	AgCl plated electrodes	AgCl plated electrodes
26	**Storage**		Polycarbonate cover	Optional cushion bag
27	**Alarms**	none	none	none
28	**Status display**	none	Status-line shows heart rate, scale settings, battery low	status-line in display shows mode, "good" signal, "direct" heart rate, volume setting, battery low
29	**Use with defibrillator**	safety hazard	safety hazard	safety hazard
30	**Source of user hazards**	defibrillator; bio-hazard	defibrillator; bio-hazard	defibrillator; bio-hazard
31	**Patient hazards**	bio-hazard	bio-hazard	bio-hazard
32	**Environmental hazards**	none known	none known	none known

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 9 1999

CADItec
c/o Ms. Betty Lock
Submission Correspondent
Medline Industries, Inc.
One Medline Place
Mundelein, IL 60060

Re: K990809
CADIscope Electronic Stethoscope
Regulatory Class: II (two)
Product Code: DQD
Dated: February 8, 1999
Received: March 11, 1999

Dear Ms. Lock:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in

regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J.Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. INDICATIONS FOR USE

INDICATIONS FOR USE STATEMENT

510(k) Number : K980105

Device Name: CADIscope Electronic Stethoscope

Indications for Use:

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It is intended for use as a diagnostic aid as part of a physical assessment of a patient by health care professionals or other individuals trained to administer emergency first aid or otherwise care for a patient.

It can be used for the amplification of heart, lung, blood vessel, enteral and other body sounds. When the device's integral electrodes are placed on the chest of the patient, it is capable of verifying the existence of cardiac biopotential activity. The quality of the biopotential activity display depends upon user technique and environmental conditions and it is in no way meant to be diagnostic.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990809