K051126

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510(k) Summary
As Required by 21 section 807.92 (c)

MAY 1 9 2005

1-Submitter Name: PULSONIC AG MEDICAL TECHNOLOGY
2-Address: Forrlibuckstrasse 110 Zurich, SWITZERLAND CH 8005
3-Phone: +41 (0)-272 75 03
4-Fax: +41 (0)-272 75 01
5-Contact Person: Artemio Granzotto, General Manager
6-Date summary prepared: March 7th, 2005
7-Device Trade or Proprietary Name: Cardioscope SONOPLUS 3000
8-Device Common or usual name: Electrocardiograph
9-Device Classification Name: Electrocardiograph
10-Substantial Equivalency is claimed against the following device:
CADITEC's CADISCOPE, 510k #K990809

11-Description of the Device:

This device SONOPLUS 3000 is a combination product that includes Electrocardiograph and manual Stethoscope.
It displays ECG and heart rate data with automatic pacemaker detection, auto scaling of ECG amplitudes and filtering.
A Windows-based software installed on an external computer allows for:

- creating patient database
- downloading, storing, graphically displaying as well as printing required data from device
- setting date on device
- communicating with PULSONIC website for software updates

12-Intended use of the device:

This device is a patented combination device that includes Electrocardiograph and manual Stethoscope with an integrated graphics display of ECG signal, heart rate, presence of a pacemaker, as well as a standard acoustic stethoscope that reduces interference ("Anti-Interference System")

This device is intended for use as a diagnostic aid as part of physical assessment of patient by healthcare 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, measuring, storing and transmitting to a database the 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.

SONOPLUS 3000 is not intended for use in intensive care. Simultaneous use with defibrillators is prohibited.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate devices cited above.

This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached. Indeed, this device is **SIMILAR** to the predicate device.

REFER TO MAIN SUBMISSION FOR COMPLETE DETAILS

FDA file reference number	510k # K980105
Attachments inside notification submission file	510k summary print out
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Similar
Target population	Similar
Design	Similar
Materials	Similar
Performance	Similar
Sterility	Not applicable
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Not Applicable
Anatomical sites	Identical
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Similar
Electrical safety	Similar
Thermal safety	Not applicable
Radiation safety	Not applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2005

Pulsonic AG Medical Technology
c/o Mr. Mark Job
Regulatory Technology Services, Inc.
1394 25th Street NW
Buffalo, MN 55313

Re: K051126
Trade Name: SONOPLUS 3000
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: May 2, 2005
Received: May 3, 2005

Dear Mr. Job:

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 may be obtained 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/dsma/dsmamain.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): K051126

Device Name: SONOPLUS 3000

Indications For Use:

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

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051126