

K974079

Safety and Effectiveness Summary
Formula for ArchiMed
Biosound Esaote

Safety and Effectiveness Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR 807.92(a).

807.92(a)(1)

Submitter Information

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JAN 22 1998

FDA/CDRH/ODE/DNC

OCT 29 11 14 AM '97

Contact Person: Colleen Hittle

Date: October 13, 1997

807.92(a)(2)

Trade Name: Formula for ArchiMed
Common Name: Electrocardiograph data analysis firmware
Classification Name(s): Electrocardiograph 870.2340
Classification Number: 74DPS

807.92(a)(3)

Predicate Device(s)

Esaote Formula K922703

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

CW
II

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Comparison Chart for Substantial Equivalence

General Characteristics	ESAOTE 4230 Formula for ArchiMed	ESAOTE ACTA Formula (K#922703)
Dimensions (l,w,h) in mm	78 x 66 x 144	75 x 68 x 145
Weight	80 kg	100 kg
Power Supply	100 – 115 / 200 – 230 V, 50 – 60 Hz	115 / 230 V, 50 – 60 Hz
Display	SVGA	SAME
ECG storage		
• Digital device	Floppy, HardDisk	SAME
• Remote data storage	RS232, Network	No
• Digital storage resolution	500 Hz	250 Hz
Environmental Conditions		
• Operating temperature	+10 / + 40°C	SAME
• Relative humidity	25 to 95% RH	SAME
Stress Testing Capabilities		
Baseline Filter	Linear Interpolation, programmable	SAME
12 Leads Time Alignment (Medians)	Yes	SAME
Fiducial Points Identification	Yes	SAME
ST Measurements	ST level and ST slope	SAME
Aberrant Beats Detection	Yes	SAME
Arrhythmias classification	No	No
12 Leads Continuous Digital Recording and Storage	Yes (standard)	Yes (optional)
Stress Peripherals		
• Treadmill	Trackmaster	SAME
• Bicycle	SECA	SAME
Other peripherals	Pressurometer	Pressurometer

The recommended pressurometer for Model 4230 is the Tango unit from SunTech Medical Instruments (USA).

Note: The new systems incorporate the same algorithms for baseline stabilization, template and medians update, fiducial points (and ST measurements) and aberrant beat detection than the predicate device. A description of these algorithms can be found in the User Manual.

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807.92(a)(4)

Device Description

Formula for ArchiMed (model 4230) represents a multi-channel electrocardiograph machine equipped with an SVGA monitor, a PC keyboard and a trackball. It is intended to be used for acquisition, digitization, display and recording of conventional diagnostic twelve (12) simultaneous lead ECG waveforms. The 4230 is equipped with a resting interpretation program covering adult populations. This analysis program is offered to the physician on an advisory basis only and the physician is asked to overread and validate (or change) the ECG interpretation.

Formula for ArchiMed is also equipped with software that can be used for exercise stress testing. It incorporates a hard disk with 4 serial ports to add networking capabilities and to accommodate printing to a laser printer. Such laser recording abilities have been recently adopted by Schiller (Cardiovit CS-200), whose product literature is attached in Appendix E.

807.92(a)(5)

Intended Use(s)

The Formula for ArchiMed line of electrocardiograph products is intended to be used by a physician to analyze cardiac performance.



JAN 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Colleen Hittle
Biosound Esaote, Inc.
8000 Castleway Drive
Indianapolis, IN 46250

Re: K974079
Formula for ArchiMed (Model 4230)
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: January 9, 1998
Received: January 12, 1998

Dear Ms. Hittle:

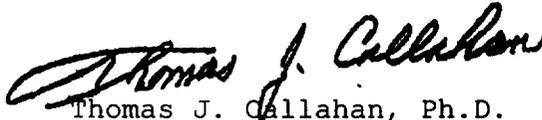
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



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

Enclosure

Indications For Use

510(k) Number (if known): K974079

Device Name: Formula for ArchiMed

Indications for Use:

The Formula for ArchiMed line of electrocardiograph products is intended to be used by a physician to analyze cardiac performance

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

 Mr. Pugh
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974079