

MAY 12 1998

K973922

Safety and Effectiveness Summary
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

Colleen Hittle, Official Correspondent
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Indianapolis, IN 46250
Phone: (317) 849-1916
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Contact Person: Colleen Hittle

Date: October 3, 1997

807.92(a)(2)

Trade Name: ArchiMed
Common Name: Electrocardiograph data analysis firmware
Classification Name(s): System, ECG Analysis 870.2340
Classification Number: 74LOS

807.92(a)(3)

Predicate Device(s)

Esaote P210 K902368

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

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Comparison Chart for Substantial Equivalence

General Characteristics	ESAOTE 4210 – 4220	ESAOTE P210 (K#902368)
Dimensions (l,w,h) in mm	328x254x75	310x350x75
Weight	3.8 kg (4210) 4.8 kg (4220)	3.3 kg
Power Supply	12V Ni-Cd rechargeable battery Mains supply 100 - 240 V, 50-60Hz	SAME SAME
Display	LCD, backlit, 480x640 pixels, adjustable viewing angle	SAME
ECG storage		
• Digital device	Floppy Disks HardDisk (Mod.4220)	RAM Cards
• Remote data storage	Yes (RS232, Network for Mod.4220)	Yes (RS232)
• Digital storage resolution	500 Hz	Up to 500 Hz
Environmental Conditions		
• Operating temperature	+10 / + 40°C	SAME
• Relative humidity	25 to 95% RH	SAME
Leads	Standard, Cabrera	SAME
ECG patient cable	10 buffered leads with RL drive Defibrillation protected	SAME SAME
Patient Input	Fully floating and isolated	SAME
ECG amplifier		
• Number of signals recorded	8 leads simultaneously acquired, 4 mathematically derived	SAME
• Sampling frequency	1000 Hz	500 Hz
• Max. DC polarization	± 450 mV	± 300 mV
• Common mode rejection	> 100 dB	SAME
• Frequency response	0.05 to > 150 Hz	SAME
Filters	50/60 Hz adaptive digital filter 30/45 Hz digital low-pass filter, programmable	SAME SAME
Recorder	Thermal print head (8 dots/mm)	SAME
• Paper speed	5, 12.5, 25, 50 mm/s	SAME
• Paper size	A4 or Letter (Z folded)	SAME, but with half length
• Recording tracks	12 channels	6 channels

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807.92(a)(4)

Device Description

The ArchiMed product line represents two (4210, 4220) versions of a portable, multi channel electrocardiograph machine. These units are intended for acquisition, digitization, display and recording of conventional diagnostic 12 simultaneous lead ECG waveforms. The 4220 model can be equipped with a resting interpretation program covering adult populations. This analysis program is offered to the physician on an advisory basis only and physician is asked to over-read and validate (or change) the ECG interpretation. Moreover, the 4220 may be equipped with a software package to be used for exercise stress testing, has wider connectivity characteristics and can print to a laser printer.

807.92(a)(5)

Intended Use(s)

The ArchiMed line of electrocardiograph products is used to record standard electrocardiographs at patient resting or exercising. Resting ECGs are automatically measured and interpreted by the optionally available interpretive software.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 1998

Biosound Esaote, Inc.
c/o Ms. Colleen J. Hittle
8000 Castleway Drive
Indianapolis, IN 46250

Re: K973922
Archimed Electrocardiographs Models 4210 and 4220
Regulatory Class: III (three)
Product Code: 74 LOS
Dated: February 10, 1998
Received: February 11, 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 (Pre-market 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.

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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): K973922

Device Name: ArchiMed

Indications for Use:

The ArchiMed line of electrocardiograph products is used to record standard electrocardiographs at patient resting or exercising. Resting ECGs are automatically measured and interpreted by the optionally available interpretive software.

(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

M. Pugh
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____