Cardiac Science Corporation
Bothell, WA
Abbreviated Premarket Notification
January 20, 2006

APR 19 2006

II. 510(k) Summary

A. Name of Device

Trade name:	Atria 3100 Atria 6100
Common name:	Electrocardiograph
Classification name:	Electrocardiograph

B. Predicate Devices

Device Name	Premarket Notification
PageWriter Trim Series Cardiograph – Phillips Medical Systems	K031422
CP 100 and CP 200 – Welch Allyn, Inc.	K050074

C. Device description

The Atria 3100 and 6100 are 12 lead electrocardiographs designed to record the electrical activity of the heart. They can display, print, electronically send and save ECG recordings. The Atria 6100 features a full alpha numeric keyboard and color display for data entry, waveform review and editing machine settings. The unit provides the ability to store 150 ECGs, print rhythm strips manually or automatically, and provides an optional interpretation. Advanced communications options allow the unit to fax, email and upload results to shared network drives via wired Ethernet, wireless 802.11 and modem.

The differences between the Atria 3100 and 6100 are as follows:

1. Screen Size:
   - Atria 3100 = 2 x 40 character display for data entry only (no waveform viewing)
   - Atria 6100 = 640 x 480 color TFT VGA preview screen for waveform viewing

2. Storage:
   - Atria 3100 = 50 records

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- Atria 6100 = 150 records

3. The Atria 6100 has a slightly different keyboard to accommodate navigation in the User Interface.

D. Intended use

Under the supervision of a qualified physician trained in ECG interpretation, Atria can be used to record the electrical activity of the heart for the purpose of correlating the resultant waveforms with the health of the heart muscle tissue structures.

This equipment is not designed to produce a definitive interpretation nor exhaustive evaluation of the patient's heart but rather provide an effective beginning for evaluation of adult and pediatric patients with cardiac abnormalities.

E. Summary

The intended use, indication for use and principle of operation are substantially equivalent to the predicate devices, and do not raise any new types of safety and effectiveness questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 19 2006

Cardiac Science Corporation
c/o Ms. Cheryl L. Shea
Vice President, RA/QA
3303 Monte Villa Parkway
Bothell, Washington 98021-8969

Re: K060167
Trade Name: Atria 3100 and Atria 6100
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: March 22, 2006
Received: March 24, 2005

Dear Ms. Shea:

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 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/industry/support/index.html.

Sincerely yours,

B Zuckerman 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

510(k) Number: K060167

Device Name: Atria 3100 and Atria 6100

Indications for Use:

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Prescription Use X 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 of Cardiovascular Devices
(510(k) Number) K060167