

MAR 21 2000

**510(k) SUMMARY**  
**K992703**  
for  
**Cardiotron LLP Inc.'s**  
**Cardiotron EKG Multi-Phase Information Analysis System**

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Premier Heart LLP  
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Date Prepared: March 20, 2000

Name of Device

Trade Name: Cardiotron EKG Multi-Phase Information Analysis System

Common Names: Computerized EKG Analysis System

Classification Names: Computerized EKG and Programmable Diagnostic Computers

Product Code: DQK

Predicate Device

New York Heart Instrument Inc.'s EKG Multi-Phase Information Diagnosis System, Model FFF-IA

Intended Use

The Cardiotron EKG Multi-Phase Information Analysis System is intended to be used as an aid to diagnosis by means of analysis of the EKG waveform in the frequency domain (power spectral estimate).

Technological Characteristics and Substantial Equivalence

The Cardiotron EKG Multi-Phase Information Analysis System will be available in two models, the basic model system and the remote model system. The basic model system consists of two standard EKG amplifiers and an off-the-shelf analog-to-digital ("A/D") converter, EKG lead wires, a computer, a monitor, and a printer. The remote model system additionally includes a dummy terminal or computer. The minor differences between the two devices is discussed in more detail below. The EKG amplifiers are supplied by the Fortune, Co. The additional components, which are off-the-shelf

products, are unmodified. The computer is programmed with the Company's multi-phase information analysis software.

To operate the system, six standard EKG leads are placed on the patient in lead positions II and V5. EKG data is collected from both leads simultaneously for approximately two to three minutes. In addition, the patient is asked, through prompts appearing on the display, approximately 78 questions related to his/her medical history, such as age, sex and smoker/non-smoker. These questions are stored in a database as a matter of convenience and as a record-keeping function and not subsequently used to provide a software-based diagnosis of the patient. For example, the Cardiotron's software has the ability to provide a partial medical history of the patient so that the physician can look up and review the answers to the questions in the software's database. The data from the EKG leads is amplified and processed, using conventional techniques, in the EKG amplifier. The data is fed from the EKG amplifier to the A/D converter, which converts the data from an analog form to a digital form. The data, which has been converted to digital form, is fed to the computer where it is transformed from the time domain to the frequency domain through the application of Fast Fourier Transform power spectrum estimate equations which have been programmed in the multi-phase analysis software installed in the computer.

The Cardiotron System and the NYHI System both consist of two EKG amplifiers, an A/D Converter, EKG lead wires, a computer programmed with software, a monitor, and a printer. Moreover, both systems use the same algorithms in their software to process the data and provide a diagnosis. The same inventor developed the software for the NYHI System and the Cardiotron System. Both systems also provide the same power spectrum estimate used in the diagnosis. Both systems also contain the same approximately 78 questions that are asked of the patient, and the answers stored in a database. The answers to the questions also are used in the identical manner as recorded in a database for the convenience of the physician. In addition, both systems provide the same ischemia indexes in the form of a positive or negative index. They also have the same sensitivities (i.e., approximately 90%) and specificities (i.e., approximately 85%).

The only difference between the two systems is the selection of components, the actual software code itself, and the Cardiotron's remote use function and associated hardware. For example, the Cardiotron System uses EKG amplifiers supplied by Fortune, Co. whereas the NYHI System's EKG amplifiers are supplied by Minta, Co. This does not raise any new issues of safety or effectiveness because both amplifiers have very similar specifications. The Cardiotron System and NYHI System use different A/D converters, EKG lead wires, computers, printers, and monitors although they provide the same basic functions. These differences also do not raise new issues of safety or effectiveness because the components are all very similar. Where there are significant differences, those differences do not affect safety or effectiveness. For example, the NYHI System does not have a high resolution color monitor whereas the Cardiotron System has a high resolution color monitor. This difference is solely for marketing purposes.

As noted above, the Cardiotron System uses slightly different code. This difference, however does not raise new issues of safety or effectiveness. First, the software code merely automates the processing of mathematical algorithms, and the mathematical algorithms in the software code of both systems are the same. The code differs only in the manner in which data is stored and in the terms used in the code. Second, as described below, the Company has validated the software to demonstrate that the software functions as intended.

Third, the use of a dummy terminal or additional computer to collect and e-mail the data to a remote location does not raise new issues of safety or effectiveness. As described below, the Company has validated the software that performs these functions. Moreover, the transmission of digital data across the internet is a common operation performed by millions of people. The concern that the data may be lost has been addressed by the Cardiotron's software, which saves the data as well as transmits the data. Thus, if the data transmitted to the remote location is for some reason "lost", it can be resent.

In summary, the Cardiotron System and its predicate device, the NYHI System, have the same intended use and very similar, principles of operation, and technological characteristics. Although there are minor difference in the actual components and software code, these differences do not raise new questions of safety or efficacy.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 21 2000

Mr. William D. Hare  
Cardiotron, LLC  
c/o Fish & Richardson, PC  
601 13<sup>th</sup> Street, N.W.  
Suite 901 South  
Washington, DC 20005

Re: K992703  
Multi-Phase EKG Information Analysis System  
Regulatory Class: II (two)  
Product Code: 74 DQK  
Dated: December 21, 1999  
Received: December 22, 1999

Dear Mr. Hare:

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 (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/dsma/dsmamain.html>".

Sincerely yours,



James E. Dillard III  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K992703

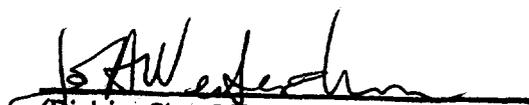
Device Name: Cardiotron Multi-Phase EKG Information Analysis System

Indications For Use:

The Cardiotron Multi-Phase EKG Information Analysis System is intended to be used as an aid to diagnosis by means of analysis of the EKG waveform in the frequency domain (power spectral estimate).

(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, Respiratory,  
and Neurological Devices  
510(k) Number K992703

Prescription Use   
Per 21 CFR 801.109)

OR

Over-The-Counter Use