CARDIOTRONICS
S Y S T E M S

K964469

510(k) Summary

Summary of information contained in the 510(k) Premarket Notification

Date:

November 5, 1996

Submitter:

Cardiotronics Systems, Inc.
5966 La Place Court
Carlsbad, California 92008

Contact Person

Tim J. Way
Vice President - Regulatory Affairs
Telephone (619) 431-9446
Facsimile (619) 431-1805

Tradename:

700-F Series Disposable Cardiac Stimulation/ Monitoring Electrodes
(a number of end products, including those manufactured under private label)

Classification:

These electrodes are disposable accessories to the following products:

Product	Code	Class	CFR Section
DC-Defibrillator, Low Energy (including paddles)	74LDD	II	870.530
Pacemaker, Cardiac, External Transcutaneous	74DRO	III	870.555

or under specific classification related to ECG monitoring would be considered:

Electrode, Electrocardiographic	74DRX	II	870.230

The 700-F series electrodes are substantially equivalent to the R2 Medical Systems 600 Series electrode.

Description:

The 700-F Series electrodes consist of a foam backing material, a laminated metallic substrate which is covered by a conductive adhesive (hydrogel). This hydrogel is then surrounded by an adhesive coated foam ring and covered by a removable release liner. The electrodes have an integral lead wire for attachment to the interface cable of the defibrillator/pacemaker/monitor.

Upon use, the release liner is removed from the electrode, exposing the hydrogel and adhesive areas. Each electrode of the set is then applied to the patient's chest in the selected set and pressed to ensure adhesion. The electrode is then attached to the host device via the interface cable and treatment is performed in accordance with established protocols.

The 700-F Series electrodes are produced in two basic styles; Adult and Child. Leadwire sets having various lengths and interface connectors are added to the basic electrode styles to obtain many combinations of end product design. The product line is further differentiated through trade name and OEM identification.

Intended Use:

The 700-F series electrodes are disposable electrodes for external cardiac stimulation and monitoring. Electrodes of this design are suitable for external pacing, external defibrillation, synchronized cardioversion and ECG monitoring. The expected patient population for the use of these devices includes adults and children. The environment for use includes all areas of the hospital, ambulance, and prehospital (paramedic) situations. Individual catalog numbers are labeled for more specific use based primarily on the interface connector and cable system which defines the host external device, such as an external defibrillator.

The devices covered by this premarket notification provide an interface from the skin to a number diagnostic or therapeutic devices and are labeled with one or more of the following intended uses:

External Defibrillation
External Pacing
ECG Monitoring
Synchonized Cardioversion

Substantial Equivalence:

Note: As used herein, the term "substantial equivalence" is only as used in 21 CFR 807.81.

The design, materials, and intended uses of the 700-F series electrodes are equivalent to the those of the R2 Medical Systems 600 Series electrodes. As in the 600 Series, the 700-F series are considered to be low impedance, large surface electrodes suitable for external defibrillation, ECG monitoring, and external pacing. Substantial equivalence has been determined primarily on the basis of electrical performance results in conformance to the AAMI standard DF39 (Subsection 3.3.19) and comparisons to materials and physical dimensions of the 600 Series.

The 700-F series electrodes differ from the 600-Series electrodes primarily in the conductive adhesive (hydrogel) material. While both hydrogels are of a similar chemical family, the 700-F series utilize a cure-in-place hydrogel manufactured by Cardiotronics while the 600 series contain a commercially available hyrdrogel suitable for this application. All other primary components and methods of manufacture are equivalent to the 600 series electrodes.

CARDIOTRONICS
S Y S T E M S

Performance Evaluation

Bench testing of the 700-F Series electrodes consisted of a battery of both electrical and mechanical tests. These tests include electrical performance parameters as indicated in ANSI/AAMI DF-39 subsection 3.3.19 as well as a number of mechanical performance parameters developed by the manufacturer. These test show the 700-F series electrodes to be suitable for the uses and environment specified.

Biocompatibility studies were conducted on the hydrogel conductive adhesive and the adhesive foam ring. The tests on the hydrogel consisted of Cytotoxicity, Primary Skin Irritation, and Delayed Contact Sensitization. Tests on the adhesive foam ring consisted of Primary Skin Insult Patch test. These tests showed all materials which contact the skin to be biocompatible.

In addition to the mechanical, electrical, and biocompatibility tests, a limited number of electrodes were tested on live pigs over a twenty four hour period to demonstrate effectiveness at delivering energy, ability to sense clear ECG signal and to ensure that these electrodes do not contribute to any significant skin changes during or after the delivery of energy.

The results of the aforementioned battery of tests demonstrate that the 700-F series electrodes are substantially equivalent to the 600 series electrodes and are suitable for the specified intended uses in the environment for use indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 26 2011

Cardiotronics Systems, Inc.
c/o Mr. Tim J. Way
5966 La Place Court
Carlsbad, CA 92008

Re: K964469
700-FR Series Stimulation Electrodes
Regulation Number: 21 CFR 870. 5300
Regulation Name: DC-Defibrillator (Including paddles)
Regulatory Class: Class II (two)
Product Code: LDD
Dated: November 5, 1996
Received: December 7, 1996

Dear Mr. Way:

This letter corrects our substantially equivalent letter of December 11, 1996.

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 (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 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for use Statement

510(k) Number K964469

Device Name : 700-F Series Disposable Stimulation Electrodes

Indications for Use:

The 700-F series electrodes are disposable electrodes for external cardiac stimulation and monitoring. Electrodes of this design are suitable for external pacing, external defibrillation, synchronized cardioversion and ECG monitoring. The expected patient population for the use of these devices includes adults and children. The environment for use includes all areas of the hospital, ambulance, and prehospital (paramedic) situations. The duration for use is intended to be less than 24 hours. Individual catalog numbers are labeled for more specific use based primarily on the interface connector and cable system which defines the host external device, such as an external defibrillator.

The devices covered by this premarket notification provide an interface from the skin to a number diagnostic or therapeutic devices and are labeled with one or more of the following intended uses:

External Defibrillation

External Pacing

ECG Monitoring

Synchonized Cardioversion

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ____ Over the Counter ____

Richard Phillips

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964469

003

4