CARDIOTRONICS
S Y S T E M S

Corporate Office
5966 LaPlace Court
Carlsbad, CA 92008

(619) 431-9446
(800) 441-9446
fax (619) 431-1805

K970719

**510(k) Summary**

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

APR 16 1997

Date:

February 15, 1997

Submitter:

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

Contact Person

Tim J. Way
Business Unit Manager
Telephone (619) 431-9446
Facsimile (619) 431-1805

Tradename:

700-MP Series Multi-pad Electrodes

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-MP series electrodes are substantially equivalent to the R2 Medical Systems 600 Series electrode and the Cardiotronics #918 Multi-pad Electrodes.

Description:

The 700-MP Radiolucent Multi-Pad 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. In addition, the 700-MP electrodes provide separate ECG monitoring elements on the same foam backing material for the attachment of standard ECG leadwires.

14-1

CARDIOTRONICS
SYSTEMS

Corporate Office
5966 LaPlace Court
Carlsbad, CA 92008

(619) 431-9446
(800) 441-9446
fax (619) 431-1805

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. Optionally, the separate leadwires may be attached to the ECG monitoring elements provided on the foam back area.

The 700-MP Radiolucent Multi-Pad electrodes are produced only in the Adult configuration. Leadwire sets having various lengths and interface connectors are added to the basic electrode style and may result in different catalog numbers to obtain combinations of end product design. The product line is further differentiated through trade name identification.

Intended Use:

The 700-MP Series Radiolucent Multi-pad 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 MP designation refers to the multifunctionality of these electrodes wherein the separate ECG monitoring elements allow for continuous ECG monitoring through the attachment of separate ECG leadwires. The radiolucent substrate of these electrodes makes them particularly well suited for certain clinical applications involving radiographic viewing. The expected patient population for the use of these devices is primarily adults. 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

As with all electrodes of this type, labeling indicates that separate ECG electrodes are required for monitoring during external pacing. In the case of 700-MP Radiolucent Multi-Pad Electrodes these separate ECG monitoring electrodes are provided on the same foam backing for the optional attachment of separate ECG leadwires.

CARDIOTRONICS
SYSTEMS

Corporate Office
5966 LaPlace Court
Carlsbad, CA 92008

(619) 431-9446
(800) 441-9446
fax (619) 431-1805

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-MP Series Radiolucent Multi-Pad electrodes are equivalent to the those of the R2 Medical Systems 600 Series electrodes and the configuration of the 700-MP electrodes are equivalent to the Cardiotronics Systems #918 Multi-pad. As in the 600 Series, the 700-MP 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 and #918 Multi-pad.

The 700-MP Series Radiolucent Multi-pad 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-MP 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.

Performance Evaluation

Bench testing of the 700-MP Series radiolucent Multi-pad 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-MP 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 of similar construction 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. Additional electrodes of similar construction were tested on live pigs over an eight hour period to demonstrate effectiveness at delivering energy, ability to sense clear ECG signals and to ensure that these electrodes do not contribute to any significant skin changes during or after delivery of energy.

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