K982835

OCT 29 1998

Summary of Safety and Effectiveness

Trade Name:

Cardima EP SELECT Switchbox

Owner:

Cardima, Inc.
47266 Benicia Street
Fremont, CA 94538-7330
Contact: Jack P. Douglas, Ph.D.
Establishment Registration Number: 9007594

Classification Name:

Electrode Recording Catheter (21 CFR 870.1220)

Device Classification:

Class II (21 CFR 870.1220) Panel: Circulatory System Devices Panel, DCRND

Intended Use and Product Description:

The Cardima EP SELECT Switchbox is a passive switching unit used in conventional electrophysiology (EP) diagnostic procedures. It is designed to provide a convenient means by which the user can record or pace from multiple unipolar or bipolar intracardiac electrodes. The device is designed to be placed on a horizontal surface or at the patient's side. It is designed to accept up to eight electrodes using standard pin connectors typically found in the EP lab. Switching between record or pace modes is accomplished by a simple switch for each electrode.

Sterilization, Packaging and Pyrogenicity:

The EP SELECT is individually packaged non-sterile in plastic wrap and cardboard box.

Substantial Equivalence:

The EP SELECT is a modified version of other conventional accessory switchboxes found in EP mapping systems. Establishment of equivalence was based on similarities of labeling, design, and functionality with the Webster CES-500 switching system.

Summary of Safety and Effectiveness:

Safety and effectiveness were established through a "Declaration of Conformity", in part, with recognized consensus standards using International Electrotechnical Commission (IEC) electromechanical standard IEC-60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety. The results show that the switchbox meets conformance with the standard and is thus safe and effective for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1998

Dr. Jack Douglas
Manager, Regulatory Affairs
CARDIMA, Inc.
47266 Benicia Street
Freemont, CA 94539-1372

Re: K982835
Electrode Switchbox, Model 11-081002
Regulatory Class: II (two)
Product Code: 74 DRF
Dated: October 14, 1998
Received: October 15, 1998

Dear Dr. Douglas:

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.

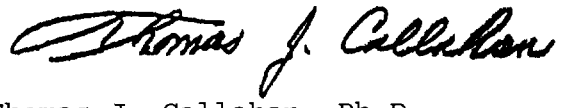
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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 (21CFR 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5 1 0(k) Number (if known): K 982835

Device Name: **Cardima EP SELECT Switchbox**

Indications For Use:

The Cardima EP SELECT Switchbox is an accessory intended to provide selective connection of multi-electrode catheters for electrogram recording and pacing during diagnostic electrophysiology studies.

(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 K982835

Prescription Use X **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801. 109)

(Optional Format 1-2-96)