This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
Date Prepared: June 17, 2002

510(k) number: K022008

JAN 2 9 2003

Applicant Information:
Cardimal, Inc.
47266 Benicia Street
Fremont, CA 94538-7330

Contact Person
Marianne Baldwin
Phone Number: (510) 354-0330
Fax Number: (510) 657-4476

Device Information:

Classification:	Class II
Trade Name:	Cardima® Ablation System
Classification Name:	Electrosurgical Cutting and Coagulating Device

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the Boston Scientific Electrosurgical Probe (K981981), the AtriCure Bipolar Coagulator (K011722); and the Medtronic Cardioblate Surgical Ablation Pen (K013392).

Intended Use:
The Cardima Ablation System is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy

Test Results:
Performance
Results of in-vitro testing demonstrate that the Cardima Ablation System is safe and effective for its intended use.

Biocompatibility
The materials used in the Cardima Ablation System meets the requirements of ISO 10993-1.

Summary: Based on the intended use, product, performance and biocompatability information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2008

Cardima, Inc.
c/o Robert A. Chin, Ph.D.
Regulatory Consultant
25 Hartford Avenue
San Carlos, CA 94070

Re: K022008
Trade/Device Name: Cardima Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulating device and accessories
Regulatory Class: Class II (two)
Product Code: OCL
Dated: November 15, 2002
Received: November 19, 2002

Dear Dr. Chin:

This letter corrects our substantially equivalent letter of January 29, 2003.

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), 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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 (if known): K022008

Device Name: Cardima® Ablation System

Indications for Use:

The Cardima Ablation System is intended to ablate cardiac tissue during cardiac surgery using radiofrequency energy

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022008

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)