K022584

DEC 3 0 2002

510(k) Summary

CardioTech Antibiotic Hydrogel Wound Dressing

Submitters Details:

CardioTech International, Inc.
78-E, Olympia Avenue,
Woburn, MA 01801-2057
Tel: (781) 933-4772
Fax: (781) 933-3933

Contact Person:

Michael Szycher, Ph.D.
Chairman and CEO
CardioTech International, Inc.
Tel: (781) 933-4772
Fax: (781) 933-3933

Name of Device:

Classification Name: Dressing, Wound
Common Name: Dressing
Proprietary Name: CardioTech Antibiotic Hydrogel Wound Dressing
Device Classification: Unclassified.

Substantial Equivalence:

CardioTech Antibiotic Hydrogel Wound Dressings are substantially equivalent to MEDIMAC Bandages (Enquay Pharmaceutical Associates, K930457) and Adhesive Bandage with Antibiotic (Johnson & Johnson, K943314).

Description:

CardioTech Antibiotic Hydrogel Wound Dressings are semi-occlusive, and absorptive.The wound contact surface is composed of an antibiotic containing hydrogel. The OTC antibiotic mixture used consists of the following components: Neomycin Sulfate, 3.5mg, Bacitracin Zinc 500 Units and Polymyxin B Sulfate, 10,000 Units. The antibiotic mixture is present to help prevent bacterial contamination of the dressing. A second outer layer consists of a polymeric film.

Indications for Use:

CardioTech Antibiotic Hydrogel Wound Dressings are intended for use in the management of partial and full- thickness wounds. They may be used on the following wounds:

- Venous stasis ulcers
- Diabetic ulcers
- Pressure sores
- Blisters
- Superficial burns
- Abrasions and lacerations
- Donor sites

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 3 0 2002

CardioTech International, Inc.
Andrew M. Reed, Ph.D.
12106 West 75th Lane
Arvada, Colorado 80005-5306

Re: K022584
Trade/Device Name: CardioTech Antibiotic Hydrogel Wound Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: October 31, 2002
Received: November 7, 2002

Dear Dr. Reed:

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 application (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 such 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 begin 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 (301) 594-4659. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT

510(k) Number: K022584
CardioTech International, Inc.

Device Name: CardioTech Antibiotic Hydrogel Wound Dressing

Indications for Use:

CardioTech Antibiotic Hydrogel Wound Dressings are intended for use in the management of partial and full-thickness wounds. They may be used on the following wounds:

- Venous stasis ulcers
- Diabetic ulcers
- Pressure sores
- Blisters
- Superficial burns
- Abrasions and lacerations
- Donor sites

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Optional Format 1-2-96)

K022584