JUN - 7 2000

K992932

510(k) Summary

Company: DMC medical limited
Unit 9 Distribution Centre
Shannon Free Trade Zone
Shannon, County Clare, Ireland

Tradename: Cardiac Insulation Pad

Classification: Class II

Description: The Cardiac Insulation Pad is a thin, pliable, foam pad which can be cut to conform to the shape of the heart. The pad covers the posterior cardiac wall or the myocardium. When the surgeon is finished using the pad, it can be easily removed by pulling the PVC locator tape. The cardiac pad is available in two sizes; adult and infant.

The Cardiac Insulation Pad isolates the myocardium from warmer tissues (descending thoracic aorta, liver, and surrounding pericardial tissues) and thus reduces undesirable re-warming of the myocardium. In addition, it protects the left phrenic nerve from cold injury during local cooling of the heart.

Material: Crosslinked, closed cell polyolefin foam

Indications: The cardiac insulation pad is indicated for use in patients undergoing heart surgery where there is a need to reduce undesirable re-warming of the myocardium and protect the left phrenic nerve from cold injury during local cooling of the heart.

Performance Data: In a study conducted by Guinn GA et al in "Phrenic nerve injury during coronary artery bypass" (Texas Heart Institute Journal 1990;17:48-50), it was shown that the cardiac insulation pad prevented left-sided diaphragmatic paralysis in 52 of 58 patients. In a study conducted by Esposito RA, Spencer, FC, in "The effect of pericardial insulation on hypothermic phrenic nerve injury during open heart surgery" (Annals of Thoracic Surgery, 43:3; 1987;303-308), it was shown that a pericardial insulation pad prevented diaphragm paralysis in 83% of the patients. Thus it was concluded that the cardiac insulation pad protects the phrenic nerve from the cold during heart surgery where the heart is cooled.

Substantial Equivalence: The device is substantially equivalent to the Cardiac Insulation Pad by Shiley, Inc. (currently Sorin Biomedica , Irvine, California), per K781990 cleared on 12/04/78.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2000

Ms. Charmaine Henderson
Director of Regulatory Affairs
DMC Medical Limited
511 Catalina Road
Fullerton, CA 92835

Re: K992932
Trade Name: CIPA (Adults) and CIPI (Infants) Cardiac Insulation Pads
Regulatory Class: II (two)
Product Code: DWF
Dated: March 31, 2000
Received: April 10, 2000

Dear Ms. Henderson:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they 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 devices 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE ENCLOSURE

510k: K992932

Device: Cardiac Insulation Pad for Adults
Cardiac Insulation Pad for Infants

Indications for Use:

The cardiac insulation pad is indicated for use in patients undergoing heart surgery where there is a need to reduce undesirable re-warming of the myocardium and protect the left phrenic nerve from cold injury during local cooling of the heart.

Brian E Hanvey DCRA 6/7/00

X Prescription use

(Division Sign-Off) Over the Counter Use

Division of Cardiovascular, Respiratory, and Neurological Devices

510(k) Number