JUN - 8 2000

K991137

EnGuard™ PHX Cardioplegia Heat Exchanger

510(k) Summary of Safety and Effectiveness

Manufacturer: Minntech Corporation
Address: 14605 28th Avenue N
Mpls, MN 55447
USA

Official Contact: Robert Johnson
Vice President, Regulatory Affairs and Quality Assurance

Minntech Corporation has supplied the following information to the U.S. Food and Drug Administration to support the substantial equivalency of the EnGuard™ PHX Cardioplegia Heat Exchanger to other cardioplegia devices currently in commercial distribution in the United States.

1. Device Description

The administration of cardioplegia solution is commonly used to provide myocardial protection or controlled arrest of the heart during coronary bypass procedures. As the oxygenated blood enters the EnGuard™ device through the inlet blood port, it passes through the fiber bundle lumens where the temperature of the blood is cooled or warmed as desired by passing water of the desired temperature into the heater/cooler section of the device, which surrounds the fiber bundle. The water enters and leaves through standard Hansen connector ports molded into the polycarbonate case.

The EnGuard™ heat exchanger must be used with separately purchased, sterile tubing sets attached as explained in the labeling. These tubing sets will determine the ratio of crystalloid to blood. The Minntech device will produce cardioplegia solution at ratios of 1:1, 2:1, 4:1 and 8:1 depending upon the chosen tubing set.

2. Intended Use

The Minntech Corporation's EnGuard™ Cardioplegia Heat Exchanger is used to facilitate mixing of a patient's blood with cardioplegia solution and to cool or warm this solution prior to delivery to the patient through connected tubing sets which provide various ratios of cardioplegia solution to blood, depending upon the tubing set chosen.

3. Comparison to Another Device in Commercial Distribution Within the United States

The EnGuard™ PHX Cardioplegia Heat Exchanger is equivalent to other cardioplegia devices currently on the market. All of these devices are intended to

heat or cool and facilitate delivery of a cardioplegia/blood solution. The Medtronic Corporation's CardioTherm™ Blood Cardioplegia System (K960755), Sorin Biomedical Vanguard™ BCD Advanced Blood Cardioplegia System (K925369) and the Avecor Cardiovascular's MyoTherm Cardioplegia Delivery System (K904171) are all substantially equivalent to the EnGuard.

4. Summary

4.1 Minntech Corporation has performed functional testing to show the EnGuard™ is safe and has equivalent performance as the predicate devices.
4.2 All materials used in the product have been evaluated for biocompatibility according to EN10993.
4.3 The shelf life of the product has been evaluated to be 4 years.

5. Summary of Substantial Equivalence

Minntech Corporation has provided the above information within the 510(k) to support the claim that the EnGuard™ PHX Cardioplegia Heat Exchanger is safe and effective when used in accordance to the device labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 8 2000

Ms. Lynn Lueders
Director of Regulatory Affairs
Minntech Corp.
14605 28TH Ave. North
Minneapolis, MN 55447

Re: K991137
Trade Name: Enguard PHX Cardioplegia Heat Exchanger
Regulatory Class: II (two)
Product Code: DTR
Dated: March 15, 2000
Received: March 16, 2000

Dear Ms. Lueders:

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,

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

Indications for Use

510(k) Number (if Known): K991137

Device Name: EnGuard™ PHX Cardioplegia Heat Exchanger

Indications for Use:

The Minntech Corporation's EnGuard™ Cardioplegia Heat Exchanger is used to cool or warm cardioplegia solution prior to delivery to the patient through connected tubing sets which provide various ratios of cardioplegia solution to blood, depending upon the tubing set chosen.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per21 CFR 801.109)

OR

Over-the Counter-use ___
(Optional Format 1-1-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991137