K020998

APR - 4 2002

Sarns™ Centrifugal Pump with X-Coating

Submitter Information:

Name and Address:
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton MD 21921

Contact Person: Garry A. Courtney
Regulatory Affairs Specialist
Telephone: 1-800-283-7866, Ext. 7420

Date of Preparation: March 8, 2002

Device Names:

Proprietary Name: Sarns™ Centrifugal Pump with X-Coating
Product Code: 164275X
Common Name: Cardiopulmonary Bypass Centrifugal Pump
Classification Name: Non-Roller Type CPB Blood Pump

Predicate Device:

Terumo Cardiovascular Systems Corporation has identified the uncoated Sarns Centrifugal Pump, Product Code 164275, as the predicate device for the determination of substantial equivalence. The predicate device is cleared with Premarket Notification K915363.

Intended Use:

The Sarns™ Centrifugal Pump with X-Coating is indicated as an extracorporeal blood pump for use in cardiopulmonary bypass procedures only, and for use exclusively with Sarns centrifugal control system.

Duration for Use:

The device may be used for up to 6-hours.

Principles of Operation and Technology:

The Sarns™ Centrifugal Pump with X-Coating performs its function using centrifugal force technology. As blood enters the device via the blood inlet port, centrifugal forces created by the pump activity will propel the blood through the pump head and out of the device via a blood outlet port.

Design and Materials:
The design of the Sarns™ Centrifugal Pump with X-Coating is such that the device meets its stated intended use, and provides an acceptable level of performance and safety to the patient.

The device is a hardshell housing that contains a blood compartment and a non-blood compartment. Within the blood compartment is a rotating mechanism that imparts centrifugal force upon blood as it enters the device. The centrifugal force moves the blood out of the device via the outlet port.

The non-blood compartment is designed to magnetically couple with a pump console so that it can be electrically driven by the console.

The materials of construction for the Sarns™ Centrifugal Pump with X-Coating are the exact same materials that are used in the predicate uncoated Sarns™ Centrifugal Pump – except for the addition of X-coating to the subject device. The differences in the materials do not raise any new issues of safety or effectiveness of the device.

Performance:
Terumo Cardiovascular Systems Corporation conducted performance evaluations on the Sarns™ Centrifugal Pump with X-Coating to demonstrate its equivalence to the uncoated Sarns™ Centrifugal Pump. The following performance tests were conducted:

- Long Duration Circulation Evaluation
- Priming Volume
- De-priming Volume
- Air Handling Efficiency
- Hemolytic Effects of the Device Upon Cellular Blood Components
- Mechanical Integrity
- Strength of Tubing Connection

Substantial Equivalence Comparison:
The Sarns™ Centrifugal Pump with X-Coating is substantially equivalent to the uncoated Sarns™ Centrifugal Pump:

- Intended Use: Both the Sarns™ Centrifugal Pump with X-Coating and the predicate Sarns™ Centrifugal Pump are indicated as extracorporeal blood pumps for use in cardiopulmonary bypass procedures only, and for use exclusively with Sarns centrifugal control system.

- Principles of Operation and Technology: The Sarns™ Centrifugal Pump with X-Coating and the predicate Centrifugal Pump each utilize the same technologies in the operation of the devices. As blood enters the device via the blood inlet port, centrifugal forces created by the pump activity will propel the blood through the pump head and out of the device via a blood outlet port.

- Design and Materials: The Sarns™ Centrifugal Pump with X-Coating and the predicate Centrifugal Pump each have the same identical design. Each device is a hardshell housing that contains a blood compartment and a non-blood compartment. Within the blood compartment is a rotating mechanism that imparts centrifugal force upon blood as it enters the device. The centrifugal force moves the blood out of the device via the outlet port.

  The non-blood compartment is designed to magnetically couple with a pump console so that it can be electrically driven by the console.

  The materials of construction for the Sarns™ Centrifugal Pump with X-Coating are the exact same materials that are used in the predicate uncoated Centrifugal Pump – except for the addition of X-coating to the subject device.

- Performance: Comparisons between the performance of the Sarns™ Centrifugal Pump with X-Coating and the predicate Centrifugal Pump were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the two devices.

Substantial Equivalence Summary:
In summary, the Sarns™ Centrifugal Pump with X-Coating and the uncoated Centrifugal Pump are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the two devices do not raise new issues of safety and effectiveness.

Additional Safety Information:
- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Terumo Cardiovascular Systems Corporation conducted the biocompatibility studies recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood,

Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

Conclusion:

In summary, the Sarns™ Centrifugal Pump with X-Coating (164275X) is substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the uncoated Sarns™ Centrifugal Pump cleared under K915363.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2002

Mr. Garry A. Courtney
Regulatory Affairs Specialist
Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K020998
Trade Name: Sarns™ Centrifugal Pump with X-Coating
Regulation Number: 21 CFR 870.4360
Regulation Name: Nonroller-type cardiopulmonary bypass blood pump.
Regulatory Class: Class III (three)
Product Code: KFM
Dated: March 25, 2002
Received: March 28, 2002

Dear Mr. Courtney:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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,

Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Sarns ™ Centrifugal Pump with X-Coating

Indications For Use:

The Sarns ™ Centrifugal Pump with X-Coating is indicated as an extracorporeal blood pump for use in cardiopulmonary bypass procedures only, and for use exclusively with Sarns centrifugal control systems.

The device may be used for up to 6 hours.

Garry A. Courtney
Regulatory Affairs
Terumo Cardiovascular Systems

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020998

Prescription Use _____ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)