

K974320

FEB - 3 1998

510(k) Summary

Name of Device

Trade name:	CryoGen Cardiac Cryosurgery System
Common name:	Cryosurgical Unit and Accessories
Classification name:	Cryosurgical Unit and Accessories (21 CFR 878.4350)

Predicate devices

Device	Premarket Notification
Frigitronics CCS 100	K811390
Spemby Cardiac Cryounit and Cryoprobes	K874367
Heartport Maze System: Cryoprobe Set	K970496
CryoGen Cryosurgical System	K972662

Device description & Principle of Operation

The CryoGen Cardiac Cryosurgery System consists of three components: the disposable Control Unit, the Cryoprobe and the Console, which contains the compressors and the dewar. The CryoGen Cardiac Cryosurgery System is a cryosurgical device incorporating a gas cooled cryoprobe. Operation of the System is based on the Joule-Thomson principle in which pressurized coolants are expanded through a small orifice to produce cooling. The device is intended to destroy tissue by the application of extreme cold. Temperatures of -100 to -120 °C are developed at the tip of the cryoprobe. These temperatures are within the range of the predicate devices and are sufficient to achieve the desired tissue effect. None of the coolant comes into contact with the patient or physician. In addition, none of the coolant gases are exhausted into the atmosphere, the system is closed. There is no cooling along the shaft of the probe nor at the handle that is held by the user during treatment.

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Intended use

The CryoGen Cardiac Cryosurgery System, as well as the other predicate devices, are intended for use in minimally invasive surgical procedures, including the treatment of cardiac arrhythmias. The cardiac cryoprobes freeze the target tissue and block in the electrical conduction pathway by creating an inflammatory response, or cryonecrosis.

Technological characteristics

The technological characteristics of the CryoGen Cardiac Cryosurgical System are the same as those of the predicate CryoGen Cryosurgical System. These devices are substantially equivalent in terms of design, materials, principle of operation, product specifications and sterilization.

Summary

By virtue of design, materials, function and intended use, the CryoGen Cardiac Cryosurgical System is substantially equivalent to the CryoGen Cryosurgical System which is cleared under K972662. It is also equivalent to the predicate devices cleared via the Premarket Notification process, which have been included in this submission.



FEB 21 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Cryogen, Incorporated
c/o Ms. Cheryl L. Shea
Vice President, Regulatory Affairs and Quality Assurance
6199 Cornerstone Court East, Suite 106
San Diego, CA 92121

Re: K974320
Trade Name: Cryogen Cardiac Cryosurgical System
Regulatory Class: II (two)
Product Code: OCL
Dated: November 14, 1997
Received: November 17, 1997

Dear Ms. Shea:

This letter corrects our substantially equivalent letter of February 3, 1998.

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.

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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" (21 CFR 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 Statement

Device Name: CryoGen Cardiac Cryosurgical System
510(k) Number:

Indications for use:

The CryoGen Cardiac Cryosurgical System is indicated for use in minimally invasive cardiac surgery procedures, including surgical treatment of cardiac arrhythmias. The cardiac cryoprobes freeze the target tissue and block the electrical conduction pathway by creating an inflammatory response, or cryonecrosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

K974320

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use _____