



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 21 2008

Heartport  
c/o Ms. Marianne C. Drennan  
Regulatory Affairs Specialist  
200 Chesapeake Drive  
Redwood City, CA 94063

Re: K970496  
Trade Name: Heartport™ Maze System Cryoprobe Set  
Regulation Number: 21 CFR 878.4350  
Regulation Name: Cryosurgical unit and accessories  
Regulatory Class: II (two)  
Product Code: OCL  
Dated: February 7, 1997  
Received: February 10, 1997

Dear Ms. Drennan:

This letter corrects our substantially equivalent letter of May 9, 1997.

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.

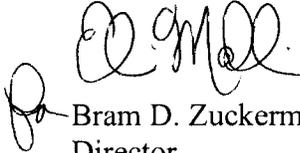
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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" (21CFR 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

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**APPENDIX A. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K970496

MAY - 9 1997

**Applicant Information:**

Date Prepared: February 7, 1997.  
Name: Heartport, Inc.  
Address: 200 Chesapeake Drive  
Redwood City, CA 94063  
Contact Person: Marianne C. Drennan  
Regulatory Affairs Specialist  
Phone Number: (415) 482-4405  
Fax Number: (415) 482-4346

**Device Information:**

Classification: Class II  
Trade Name: Heartport™ Maze System: Cryoprobe Set  
Common Name: Cryosurgical unit and accessories  
Product Code: GEH

**Equivalent Devices:**

The Heartport™ Maze System: Cryoprobe Set is substantially equivalent in intended use and/or method of operation to the following predicate devices:

1. Frigitronics® CCS-200 Cardiac Cryosurgical System
2. Spembyl Medical - Cardiac Cryounit and associated Cardiac Cryoprobes

**Intended Use:**

The Heartport™ Maze System: Cryoprobe Set is intended for use in minimally invasive cardiac surgery procedures, including the surgical treatment of cardiac arrhythmias. The cryoprobes are applied to tissue and frozen to cause a block of electrical conduction through tissue by way of an inflammatory response, or cryonecrosis. The Set includes probes of varied tip shapes to optimize access to the treatment site.

**510(k) Summary of Safety and Effectiveness (continued)****Comparison To Predicate Devices:**

The Heartport™ Maze System: Cryoprobe Set is equivalent in intended use and operational characteristics to the Frigitrronics® Cryoprobes and the Spemby Medical Cardiac Cryoprobes. The Heartport™ Maze System: Cryoprobe Set is specifically designed for introduction and use via a trocar or incision in minimally invasive cardiac surgery procedures.

**Non-Clinical Test Results:***Performance*

Heartport™ Maze System: Cryoprobe Set meets the applicable sections of ASTM F 882 - 84 *Standard Performance and Safety Specification for Cryosurgical Medical Instruments*.

*Biocompatibility*

The materials used to fabricate the Heartport™ Maze System: Cryoprobe Set are similar to the predicate devices. All materials used in the Heartport™ Maze System: Cryoprobe Set have established biocompatibility.

**Summary:**

Based on the intended use, product information, performance data and biocompatibility information provided in this premarket notification, the Heartport™ Maze System: Cryoprobe Set has been shown to be substantially equivalent to currently marketed predicate devices.