

K979175

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

This summary of 510(k) 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: _____

DEC 16 1997

Applicant Information:

Date Prepared: November 5, 1997

Name: Heartport, Inc.
Address: 200 Chesapeake Drive
Redwood City, CA 94063

Contact Person: Marianne C. Drennan
Phone Number: (650) 482-4405
Fax Number: (650) 482-4346

Device Information:

Trade Name: Heartport® Endoaortic Clamp™ Catheter
Classification Name: Vascular Clamp, 21 CFR 870.4450

Equivalent Devices:

The subject device is substantially equivalent in intended use and method of operation to the currently marketed Heartport® Endoaortic Clamp™ catheter and the Medi-tech Occlusion Balloon catheter.

Intended Use:

The Heartport Endoaortic Clamp catheter is indicated for use in patients undergoing cardiopulmonary bypass. The Endoaortic Clamp catheter occludes and vents the ascending aorta when the balloon is inflated. The device's central lumen allows delivery of cardioplegia to arrest the heart. The pressure lumen allows monitoring of the aortic root pressure.

Comparison to Predicate Devices:

This device has the same intended use and technological characteristics as the predicate devices.

Non-clinical Test Results:

Based on the equivalence in design to the predicate device, performance testing was not warranted for this device. The device will meet the same criteria established for the currently marketed Heartport® Endoaortic Clamp™ catheter.



Rockville MD 20857

Ms. Marianne C. Drennan
Senior Regulatory Affairs Specialist
HeartPort, Inc.
200 Chesapeake Drive
Redwood City, CA 94063

DEC 16 1997

Re: K974175
Heartport® Endoaortic Clamp™ Catheter
Regulatory Class: II (Two)
Product Code: DWZ
Dated: November 5, 1997
Received: November 6, 1997

Dear Ms. Drennan:

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 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 (Pre-market 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 pre-market 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.

Page 2 - Ms. Marianne C. Drennan

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" (21 CFR 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/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

