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

The assigned 510(k) number is: _____

Applicant Information:

Date Prepared:	December 15, 1999
Name:	Heartport, Inc.
Address:	700 Bay Road Redwood City, CA 94063
Contact Person:	Marianne C. Drennan
Phone Number:	(650) 482-4405
Fax Number:	(650) 482-4346

Device Information:

Trade Names:	Heartport® DirectFlow™ Kit, DirectFlow™ Cannula Heartport SoftClamp™ Kit, SoftClamp™ Cannula Heartport StraightShot™ Kit, StraightShot™ Cannula Heartport AutoIncisor™ Introducer
Classification Name:	Cardiovascular Surgical Devices - Cardiopulmonary bypass vascular cannula

Equivalent Devices:

The subject device is substantially equivalent in intended use, technological characteristics, and materials to currently marketed Heartport arterial kits.

Intended Use:

The DirectFlow™ Kit, SoftClamp™ Kit and StraightShot™ Kit are indicated for patients undergoing cardiopulmonary bypass. The DirectFlow, SoftClamp and StraightShot arterial cannulae are intended to deliver oxygenated blood for cardiopulmonary bypass. The DirectFlow and SoftClamp arterial cannulae also allow the hemostatic introduction and removal of the Heartport EndoClamp™ aortic catheter. The DirectFlow arterial cannula is intended for introduction and use through a thoracic trocar or incision.
The AutoIncisor introducer is intended for use with Heartport arterial cannulae. It is intended for incising the aorta and introducing the cannula into the aorta.

Comparison to Predicate Devices:

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

Non-clinical Test Results:

Performance testing demonstrated that the subject device meets established specifications.

Summary:

Based on the intended use, product performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2000

Ms. Marianne C. Drennan
Senior Manager, Regulatory Affairs
HeartPort
700 Bay Road
Redwood City, CA 94063

Re: K994243/S2
Heartport® arterial cannulae
Regulatory Class: II (two)
Product Code: DWF
Dated: April 17, 2000
Received: April 18, 2000

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 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) 594-4692. 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,

Brian E. Hanegan for

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

Enclosure

APPENDIX D. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K994243

Device Name: DirectFlow™ Kit, SoftClamp™ Kit, StraightShot™ Kit

Indications for Use:

The DirectFlow™ Kit, SoftClamp™ Kit and StraightShot™ Kit are indicated for patients undergoing cardiopulmonary bypass. The DirectFlow, SoftClamp and StraightShot arterial cannulae are intended to deliver oxygenated blood for cardiopulmonary bypass. The DirectFlow and SoftClamp arterial cannulae also allow the hemostatic introduction and removal of the Heartport EndoClamp™ aortic catheter. The DirectFlow arterial cannula is intended for introduction and use through a thoracic trocar or incision. The AutoIncisor introducer is intended for use with Heartport arterial cannulae. It is intended for incising the aorta and introducing the cannula into the aorta

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over- The Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K994243