APPENDIX B. 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: _____

Applicant Information:

Date Prepared:	December 18, 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:

Classification	Class II
Trade Name:	Heartport® Direct Aortic Return Cannula with Introducer
Classification Name:	Cardiovascular Surgical Devices - Cardiopulmonary bypass vascular cannula (21 CFR 870.4210); Catheter introducer (21 CFR 870.1340)

Equivalent Devices:
The subject device is substantially equivalent in intended use and method of operation to the currently marketed Heartport® Direct Aortic Return Cannula, the Heartport® Endoarterial Return™ Cannula and the Cardiovascular Research, Inc. Cannula Introducer.

Intended Use:
The Direct Aortic Return Cannula is indicated for patients undergoing cardiopulmonary bypass. It is intended to deliver oxygenated blood for cardiopulmonary bypass during surgery. The Direct Aortic Return Cannula also allows the hemostatic introduction and removal of vascular catheters such as the Heartport® Endoaortic Clamp™ catheter. The cannula may be introduced through a 12mm or larger trocar or incision.

The Cannula Introducer is intended for use with Heartport arterial return cannulae. It is intended for incising the vessel and introducing the cannula into the vessel.

Non-Clinical Test Results:

Performance testing demonstrated that the Heartport Direct Aortic Return Cannula with Introducer meets established specifications. The materials used in the Heartport Direct Aortic Return Cannula with Introducer have proven biocompatibility.

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

JUL 15 1998

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

Re: K974736
HeartPort® Direct™ Aortic Return Cannula with Introducer
Regulatory Class: II (Two)
Product Code: DWF
Dated: May 22, 1998
Received: May 26, 1998

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) 594-4648. 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/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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

Indications for Use

510(k) Number (if known): K974736

Device Name: Heartport® Direct Aortic Return Cannula with Introducer

Indications for Use:

The Direct Aortic Return Cannula is indicated for patients undergoing cardiopulmonary bypass. It is intended to deliver oxygenated blood for cardiopulmonary bypass during surgery. The Direct Aortic Return Cannula also allows the hemostatic introduction and removal of vascular catheters such as the Heartport® Endoaortic Clamp™ catheter. The cannula may be introduced through a 12mm or larger trocar or incision.

The Cannula Introducer is intended for use with Heartport arterial return cannulae. It is intended for incising the vessel and introducing the cannula into the vessel.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974736

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