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:	March 17, 1998
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® Endopulmonary Vent™ catheter
Classification Name:	Cardiopulmonary bypass catheter

Equivalent Devices:

The modified Heartport® Endopulmonary Vent™ catheter is equivalent in intended use and technological characteristics to the currently marketed Heartport® Endopulmonary Vent™ catheter.

Intended Use:

The Heartport® Endopulmonary Vent™ catheter is indicated for use in patients undergoing cardiopulmonary bypass. It is intended to remove blood from the pulmonary artery and assist in decompressing the heart.

Non-Clinical Test Results:

Performance testing demonstrated that the Heartport® Endopulmonary Vent™ catheter meets established specifications. The materials used in the Heartport® Endopulmonary Vent™ catheter 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

SEP 4 1998

Ms. Lisa McGrath
Sr. Regulatory Affairs Specialist
HeartPort, Inc.
200 Chesapeake Drive
Redwood City, CA 94063

Re: K981009
HeartPort® Endopulmonary Vent™ Catheter
Regulatory Class: II
Product Code: DWF
Dated: July 16, 1998
Received: July 17, 1998

Dear Ms. McGrath:

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 Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K981009

Device Name: Heartport® Endopulmonary Vent™ catheter

Indications for Use:

The Heartport Endopulmonary Vent Catheter is indicated for use in patients undergoing cardiopulmonary bypass. It is intended to remove blood from the pulmonary artery and assist in decompressing the heart.

(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 K981009

Prescription Use X
(Per 21 CFR 801.109)

OR

Over- The Counter Use _____
(Optional Format 1-2-96)