Appendix A. 510(k) Summary of Safety and Effectiveness

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: _____

Applicant Information:

Date Prepared:	March 29, 1996
Name:	Heartport, Inc.
Address:	200 Chesapeake Drive Redwood City, CA 94063
Contact Person:	Robert J. Chin
Phone Number:	(415) 306-7900
Fax Number:	(415) 306-7905

Device Information:

Trade Name:	Endopulmonary Vent
Common Name:	Pulmonary Vent Catheter
Classification Name:	Cardiopulmonary bypass catheter

Equivalent Devices:

Name:	Pulmonary Artery Vent Catheter
Manufacturer:	DLP
Status:	Post-enactment
510(k) #	K845046
Name:	Edslab Pulmonary Artery Catheter
Manufacturer:	Baxter Healthcare Corporation
Status:	Pre-enactment
510(k) #	not applicable
Name:	Swan-Ganz® Heparin Coated, Pulmonary Artery Catheter
Manufacturer:	Baxter Healthcare Corporation
Status:	Post-enactment
510(k) #	K811411

510(k) Summary of Safety and Effectiveness (continued)

Intended Use:

Intended for the removal of blood from the pulmonary artery and decompression of the heart during endovascular cardiopulmonary bypass.

Comparison To Predicate Devices:

This device has the same intended use as the DLP Pulmonary Artery Vent Catheter and uses a combination of the technological characteristics of the identified predicate devices.

Non-clinical Test Results:

Performance testing has demonstrated with 95% confidence that the Endopulmonary Vent will meet or exceed Heartport's performance standards.

Test Conclusions:

Performance testing has demonstrated that the Endopulmonary Vent will function safely and effectively, while meeting the anticipated clinical requirements for the intended use.