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
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Device Information:

Trade Name:	Heartport Endosinus Catheter
Common Name:	Sinus Catheter
Classification Name:	Cardiopulmonary bypass vascular catheter

Equivalent Devices:

Name:	Coronary Sinus Perfusion & Pressure Monitoring Cannula
Manufacturer:	Research Medical, Inc.
Status:	Post-enactment
510(k) #	K897137
Name:	Baim Coronary Sinus Flow Catheter
Manufacturer:	Electro-Catheter Corporation
Status:	Post-enactment
510(k) #	K810360

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

Intended Use:

Occlusion of the coronary sinus, delivery of cardioplegia, and monitoring of coronary sinus pressure during cardiopulmonary bypass.

Comparison To Predicate Devices:

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

Non-clinical Test Results:

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

Test Conclusions:

Performance testing has demonstrated that the Endosinus Catheter will function safely and efficaciously, while meeting the anticipated clinical requirements for the intended use.