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:	October 16, 1996
Name:	Heartport, Inc.
Address:	200 Chesapeake Drive Redwood City, CA 94063
Contact Person:	Kevin F. MacDonald
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Device Information:

Trade Name:	Heartport Endoaortic Clamp™
Common Name:	Endoaortic Clamp Catheter
Classification Name:	Cardiopulmonary bypass vascular catheter

Equivalent Devices:

Heartport Endoaortic Clamp - K962510
Heartport Endoaortic Clamp - K955132

Intended Use:

Occlusion of the aorta, delivery of cardioplegic solution, and monitoring of aortic root pressure during cardiopulmonary bypass.

Comparison To Predicate Devices:

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

Non-clinical Test Results:

Performance testing has demonstrated with 95% confidence that the Heartport Endoaortic Clamp™ will meet or exceed Heartport, Inc. performance standards.

Test Conclusions:

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