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:	June 26, 1996
Name:	Heartport, Inc.
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Device Information:

Trade Name:	Endoaortic Clamp (Catalog Number 02055)
Common Name:	Endoaortic Clamp Catheter
Classification Name:	Cardiopulmonary bypass vascular catheter

Equivalent Devices:

Heartport Endoaortic Clamp (Catalog Number 01055)

Intended Use:

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

Comparison To Predicate Devices:

The modifications to the predicate device provides the surgeon with an endoaortic clamp already preassembled with the necessary accessories in one sterile package.

Non-clinical Test Results:

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

Test Conclusions:

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