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

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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:	November 6, 1995
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Device Information:

Trade Name:	Endoarterial Return Cannula
Common Name:	Arterial Return Cannula
Classification Name:	Cardiopulmonary bypass vascular cannula

Equivalent Devices:

Bio-Medicus Cannula-Tubing
Tuohy-Borts Y Hemostasis Valve

Device Descriptions:

Cannula-Tubing
This post-enactment device is an extracorporeal cannula used to cannulate vessels, perfuse vessels or organs, and/or connect with accessory extracorporeal equipment.

Tuohy-Borts Y Hemostasis Valve
This post-enactment device is a hemostatic valve mounted on a "Y" connector attached on the distal (hub) end of a guiding (large bore) catheter. The device is intended for use in: pressure monitoring, flushing, infusion, and guiding catheter insertion for balloon dilatation angioplasty.

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

Intended Use:
Use of the endoarterial return cannula is indicated for patients undergoing endovascular cardiopulmonary bypass. The endoarterial return cannula serves to deliver oxygenated blood for cardiopulmonary bypass during cardiac surgery and to allow hemostatic introduction, removal and securing of the endoaortic clamp catheter into the femoral artery.

Comparison To Predicate Devices:
The Endoarterial Return Cannula is not significantly changed from the predicates. The only difference is the addition of an inner and outer tip coating to enhance lubricity during insertion of catheters. The Endoarterial Return Cannula provides the surgeon with one device that can be utilized to both introduce catheters and maintain cardiopulmonary by-pass.

Non-clinical Test Results:
Performance testing has demonstrated with 95% confidence that the endoarterial return cannula will meet or exceed Heartport, Inc. performance standards.

Test Conclusions:
Performance testing has demonstrated that the endoarterial return cannula will function safely and efficaciously, while meeting the anticipated clinical requirements for the intended use.