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:	July 18, 1996
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Device Information:

Trade Name:	Heartport Endovenous Drainage Cannula
Common Name:	Venous Cannula
Classification Name:	Cardiopulmonary bypass vascular cannula

Equivalent Devices:

Medtronic DLP, Inc. - Femoral Venous Cannula
Research Medical, Inc. - Fem-flex Femoral Access Cannulae

Intended Use:

Use of the Heartport Endovenous Drainage Cannula is indicated for patients undergoing endovascular cardiopulmonary bypass. The Heartport Endovenous Drainage Cannula serves to drain non-oxygenated blood for cardiopulmonary bypass during cardiac surgery.

Comparison To Predicate Devices:

The Heartport Endovenous Drainage Cannula is not significantly different from the identified predicates. The only difference is the addition of a surface coating to enhance lubricity during insertion of the cannula.

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

Non-clinical Test Results:
Performance testing has demonstrated that the Heartport Endovenous Drainage Cannula provides comparable flow rates to the identified predicate devices.

Test Conclusions:
Performance testing has demonstrated that the Heartport Endovenous Drainage Cannula will function safely and efficaciously, while meeting the anticipated clinical requirements for the intended use.