K962858

SEP 30 1996

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 19, 1996
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Device Information:

Trade Name:	Endovascular Cardiopulmonary Bypass Systems
Common Name:	Cardiopulmonary bypass catheter kits
Classification Name:	Cardiopulmonary bypass vascular catheter

Equivalent Devices:

The Heartport Endovascular Antegrade Cardiopulmonary Bypass System is composed of the following commercially available bypass catheters, cannulae and accessories:

Heartport Endoaortic Clamp (K955132)
Heartport Endopulmonary Vent (K961245)
Heartport Endoarterial Return Cannula (K955121)
Medtronic DLP Venous Drainage Cannula (K875353) or a substantially equivalent Heartport manufactured device

The Heartport Endovascular Antegrade/Retrograde Cardiopulmonary Bypass System consists of the above Antegrade Kit in addition to:

Heartport Endosinus Catheter (K961270)

Intended Use:

The Heartport Endovascular Cardiopulmonary Bypass Systems are indicated for use in patients undergoing cardiac surgery requiring cardiopulmonary bypass and an arrested heart. The system consists of a set of catheters, cannulae and accessories that permits a patient to be maintained on cardiopulmonary bypass and the patient's heart to be arrested without the need for a median sternotomy.

Comparison To Predicate Devices:

There are no changes from the predicate devices other than the shelf packaging and its label.