

**Appendix E. 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: K955132

**Applicant Information:**

Date Prepared: November 2, 1995

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**Device Information:**

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

**Equivalent Devices:**

Medi-tech Occlusion Balloon Catheter  
RMI Coronary Sinus Perfusion & Pressure Monitoring Cannulae  
Cooley Aortic Clamp  
DLP Cardioplegia Pressure Cannula with Vent Line  
Datascope PERCLUDER™ - DL Occluding Balloon  
Fogarty Occluding Catheter

**Predicate Device Descriptions:****Medi-tech Balloon Occlusion Catheter**

This predicate is a pre-enactment device commercially distributed in multiple sizes. This device is a multi-lumen latex balloon catheter which occludes vasculature through one lumen, and delivers contrast material or therapeutic agents through the second lumen.

**The RMI Coronary Sinus Perfusion & Pressure Monitoring Cannula**

The cannula is a post-enactment device distributed in multiple sizes. This device is a multi-lumen latex balloon cannula which occludes the coronary sinus, perfuses cardioplegia, and monitors pressure.

**Cooley Aortic Clamp**

This pre-enactment device is a stainless steel mechanical anastomosis clamp manufactured by Baxter Healthcare Corporation. The device is available in a variety of sizes, with varied jaw angles. It is intended to physically clamp the exterior of the aorta causing total occlusion.

**DLP Cardioplegia Pressure Cannula with Vent Line**

This post-enactment device is an aortic root cannula with a vent line manufactured by Medtronic, Inc.. The device is intended to deliver cardioplegia, monitor aortic root pressure, and provide venting.

**Datascope PERCLUDER™ - DL Occluding Balloon**

This post-enactment device is an occluding balloon manufactured by Datascope. The device is indicated for use in internally occluding the aortic arch during cardio-pulmonary bypass grafting.

**Fogarty Occluding Catheter**

This pre-enactment device is an occluding balloon catheter manufactured by Baxter Healthcare. This device is indicated for use in internally occluding the aorta and delivering chemotherapeutic agents.

**Intended Use:**

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

**Comparison To Predicate Devices:**

This device combines the same functions as the individual predicate devices, into a single catheter.

**Clinical Test Results:**

The Heartport Endoaortic Clamp Catheter successfully maintained cardiopulmonary pass in ten subjects of a clinical investigation.

**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.