

JAN 22 1997

Endocoronary Sinus™ Catheter

K964248

Appendices

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**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: October 22, 1996

Name: Heartport, Inc.  
Address: 200 Chesapeake Drive  
Redwood City, CA 94063

Contact Person: Kevin F. MacDonald  
Phone Number: (415) 306-7900  
Fax Number: (415) 306-7905

**Device Information:**

Trade Name: Heartport Endocoronary Sinus Catheter  
Common Name: Sinus Catheter  
Classification Name: Cardiopulmonary bypass vascular catheter

**Equivalent Device:**

Name: Endosinus Catheter  
Manufacturer: Heartport, Inc.  
Status: Post-enactment  
510(k) #: K961270                      Cleared: June 18, 1996

**510(k) Summary of Safety and Effectiveness** (continued)**Intended Use:**

The catheter is designed to provide occlusion of the coronary sinus, to deliver cardioplegic solution to the coronary sinus and to monitor the coronary sinus pressure during cardiopulmonary bypass.

**Comparison To Predicate Devices:**

This device has the same intended use and technological characteristics as the predicate device.

**Non-clinical Test Results:**

Performance testing has demonstrated with 95% confidence that the Endocoronary Sinus Catheter will meet or exceed Heartport's performance standards.

**Test Conclusions:**

Performance testing has demonstrated that the Endocoronary Sinus Catheter will function safely and effectively, while meeting the anticipated clinical requirements for the intended use.