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**APPENDIX B. 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:

K905051

MAR 12 1997

**Applicant Information:**

Date Prepared: December 17, 1996

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**Device Information:**

Classification: Class II  
Trade Name: Heartport™ Needle Trocar  
Classification Name: Cardiovascular Devices - Trocar  
21 CFR 870.1390

**Equivalent Devices:**

The Heartport Needle Trocar is substantially equivalent in intended use and/or method of operation to the Heartport Surgical Thoracic Trocar and the Popper & Sons Biopsy Needle.

**Intended Use:**

The Heartport Needle Trocars are intended to provide access to the thoracic cavity. The Heartport Needle Trocar allows suture snares and similar small devices to be inserted and used during minimally invasive cardiothoracic surgery procedures.

**Comparison To Predicate Devices:**

The Heartport Needle Trocars are equivalent in intended use to the Heartport Surgical Thoracic Trocars. They are equivalent in operational characteristics to the Popper & Sons Biopsy Needles.

**510(k) Summary of Safety and Effectiveness, continued****Non-Clinical Test Results:***Performance*

The Heartport Needle Trocar is identical to the Popper & Sons Biopsy Needle in design and performance characteristics. As this predicate device has been successfully marketed for many years with well established performance, no further testing is warranted.

*Biocompatibility*

The materials used in the Heartport Needle Trocar have proven biocompatibility.

**Summary:**

Based on the intended use, product, performance and biocompatibility information provided in this Notification, Heartport Needle Trocars have been shown to be substantially equivalent to a combination of currently marketed predicate devices.