

APPENDIX A. 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: K961463

OCT - 8 1996

Applicant Information:

Date Prepared: April 16, 1996
Name: Heartport, Inc.
Address: 200 Chesapeake Drive
Redwood City, CA 94063
Contact Person: Isabella Abati
Phone Number: (415) 306-7900
Fax Number: (415) 306-7905

Device Information:

Classification: Class II
Trade Name: Heartport™ Thoracic Surgical Trocar
Common Name: Trocars
Classification Name: Trocars: Cardiovascular Devices - Trocar, 21 CFR 870.1390

Equivalent Devices:

The Heartport Thoracic Surgical Trocars are substantially equivalent in intended use and/or method of operation to a combination of the following predicate devices:

1. U.S. Surgical - Auto Suture Thoracoport 11.5 mm Disposable Trocar
2. Origin Medsystems (a Guidant Corp.) - Surgical Trocar Thoracic
3. Ethicon (a Johnson & Johnson co.) - Endopath Thoracic Trocar Sleeve with Rounded Tip Obturator
4. Snowden-Pencer - Reusable Thora-Port
5. Deknatel - Gabby-Frater Suture Guide

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

Heartport Thoracic Surgical Trocars are intended to provide access to the thoracic cavity through ports in the intercostal spaces, with minimal to no rib retraction. The Heartport Thoracic Trocar allows endoscopic instruments, thoroscopes and accessory devices to be inserted and used during cardiac surgery procedures. The trocar cannula may also be used for suture organization.

Comparison To Predicate Devices:

The Heartport Thoracic Surgical Trocars are equivalent in intended use and operational characteristics to the following devices: (1) U.S. Surgical - Auto Suture Thoracoport 11.5 mm Disposable Trocar, (2) Origin Medsystems (a Guidant Corp.) - Surgical Trocar Thoracic, (3) Ethicon (a Johnson & Johnson co.) - Endopath Thoracic Trocar Sleeve with Rounded Tip Obturator, (4) Snowden-Pencer - Reusable Thora-Port and (5) Deknatel - Gabby-Frater Suture Guide.

The Heartport Thoracic Surgical Trocars combine the same functions as the individual predicate devices into a single device. Heartport Thoracic Surgical Trocars may be used with the Heartport Oval Light accessory device to provide illumination to the surgical site.

Non-Clinical Test Results:*Performance*

The Heartport Thoracic Surgical Trocar was evaluated *in vitro* for performance including compatibility with endoscopic instruments and suture organization ability. In addition, the Thoracic Surgical Trocar was evaluated during *in vivo* studies. Performance testing demonstrated that the Heartport Surgical Thoracic Trocar was safe and effective, while meeting the anticipated clinical requirements for its intended use.

Biocompatibility

The materials used to fabricate the Heartport Thoracic Surgical Trocar and Oval Light are the same as, and in most cases identical to, the predicate devices. The materials used in the Heartport Thoracic Surgical Trocar and Oval Light have proven biocompatibility.

Summary:

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