

**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:           K961334          

**Applicant Information:**

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**Device Information:**

Classification	Class II
Trade Name:	Handswitch Electrocautery Probe
Common Name:	Electrocautery Probe
Classification Name:	21 CFR 878.4400 Electrosurgical Cutting and Coagulation Device and Accessories 21 CFR 884.4120 Gynecologic Electrocautery and Accessories

**Equivalent Devices:**

The Heartport Handswitch Electrocautery Probe is substantially equivalent in intended use and/or method of operation to a combination of the following predicate devices:

- 1.DLP (a division of Medtronic) - I.M.A. Electrocautery Knife Blades
- 2.Valleylab (a Pfizer company) - Disposable Handswitching Laparoscopic Handset and Laparoscopic Electrode
- 3.Ximed Medical Systems - Electroprobe Single-Use Surgical Probe

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## 510(k) Summary of Safety and Effectiveness (continued)

### Intended Use

The Heartport Handswitch Electrocautery Probe is used in conjunction with standard electrosurgical generators for the hemostatic dissection of tissue and coagulation of blood. The long, narrow shaft allows the device to be used during the endoscopic takedown of the Internal Mammary Artery. The probe's central lumen allows for the evacuation of smoke generated by electrocautery as well as the removal of fluid from the thoracic cavity. The central lumen may also be used to provide irrigation fluid to the surgical site.

### Comparison To Predicate Devices

The Handswitch Electrocautery Probe is equivalent in intended use and operational characteristics to the following devices: (1) DLP (a division of Medtronic) I.M.A. Electrocautery Knife Blades, (2) Valleylab (a Pfizer company) Disposable Handswitching Laparoscopic Handset and Laparoscopic Electrode and (3) Ximed Medical Systems Electroprobe Single-Use Surgical Probe.

The Heartport Handswitch Electrocautery Probe combines the same functions as the individual predicate devices into a single electrocautery device.

### Non-Clinical Test Results

#### *Performance:*

The Handswitch Electrocautery Probe was evaluated for its ability to dissect and cauterize tissue as well as evacuate smoke and fluid during operation. All Electrocautery Probes tested, effectively dissected and cauterized tissue, and evacuated smoke and fluids from the thoracic cavity.

#### *Biocompatibility:*

The patient contacting materials used to fabricate the Heartport Handswitch Electrocautery Probe are similar, and in most cases identical, to the materials used in the predicate devices.

### Summary

Based on the product information, intended use, performance and biocompatibility data provided in this Notification, the Heartport Handswitch Electrocautery Probe has been shown to be substantially equivalent to currently marketed predicate devices.