
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.

NOV - 7 1996

The assigned 510(k) number is:

K962366

Applicant Information:

Date Prepared: June 17, 1996

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Device Information:

Classification: Class II
Trade Name: Heartport™ Cable Bulldog Clamp
Common Name: Cardiovascular Devices - Vascular Clamp, 21 CFR 870.4450
Product Code: 74DXC

Equivalent Devices:

The Heartport Cable Bulldog Clamp are substantially equivalent in intended use and/or method of operation to a combination of the following predicate devices:

1. Baxter Healthcare - Fogarty® Spring Clips (Softjaw®, Safejaw®, and Double Safejaw® Spring Clips) and Spring Clip Applicators
2. Baxter Healthcare - EDWARDS Parallel Jaw Spring Clip and Applicator Forceps
3. Baxter Healthcare - EDWARDS Single Softjaw and Double Softjaw Handleless Clamps

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

The Heartport Cable Bulldog Clamp is intended for the temporary occlusion of a vessel, including the Internal Mammary Artery or vein grafts, and other clamping procedures. The Cable Bulldog Clamp may be introduced to surgical sites through a thoracic port or incision for use during endoscopic cardiac surgical procedures.

Comparison To Predicate Devices:

The Heartport Cable Bulldog Clamps are equivalent in intended use and operational characteristics to the following devices: (1) Baxter Healthcare - Fogarty® Spring Clips (Softjaw®, Safejaw®, and Double Safejaw® Spring Clips) and Spring Clip Applicators; (2) Baxter Healthcare - EDWARDS Parallel Jaw Spring Clip and Applicator Forceps; and (3) Baxter Healthcare - EDWARDS Single Softjaw and Double Softjaw Handleless Clamps

The Heartport Cable Bulldog Clamp combines the same functions as the individual predicate devices into a single device.

Non-Clinical Test Results:*Performance*

The Heartport Cable Bulldog Clamp was evaluated *in vitro* for clamping force. The performance testing demonstrated that the Heartport Cable Bulldog Clamp equivalent to the predicate device tested and meets the anticipated clinical requirements for its intended use.

Biocompatibility

The materials used to fabricate the Heartport Cable Bulldog are similar to the predicate devices. All materials used in the Heartport Cable Bulldog Clamp have proven biocompatibility.

Summary:

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