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K960937

SUMMARY OF SAFETY OF EFFECTIVENESS

RDI SUCTION SAFETY DEVICE

I. General Information

A. Generic Name:	Suction Safety Device
B. Trade Name of Device:	RDI Suction Safety Device
C. Applicants Name and Address:	RDI, Richardson, TX
D. Pre-market Notification Number:	Not assigned

II. Indication for Use

The RDI Suction Safety Device is intended to be used during open heart surgery and placed in a suction line to permit flow only away from the heart, prevent buildup of line pressure, and limit line vacuum.

III. Device Description

The RDI Suction Safety Device is a three function assembly that is positioned in a suction line. The Suction Safety Device contains to valves. The first valve is a check valve that insures uni-directional flow. The second valve is a combination valve that relieves excess pressure and relieves excess vacuum.

IV. Device Classification: Class II

V. Safety and Effectiveness:

Substantial Equivalence: This device has been shown to be substantially equivalent to the Delta Vacuum Relief Valve 510(k) 760894.

VI. Other Safety and Effectiveness Data:

Material: Fluid contact materials of construction comply with Tripartite Biocompatibility Guidance for external devices, blood path direct, short term use.
Sterilization: Validated AAMI/ISO Method 1 validation for Gamma radiation sterilization.
Pyrogenicity: Non-Pyrogenic
Functional Testing:

Pressure Relief:	Found to be similar to predicate
One-Way Flow:	Found to be similar to predicate
Vacuum Relief:	Found to be similar to predicate
Package Integrity:	Passed in accordance with ASTM F1140-88
Ship/Distribution:	Passed in accordance with NSTA Project 1A vibration/drop tests
Accelerated Aging	Successful two year shelf life