K964198

MAR 19 1997

SUMMARY OF SAFETY AND EFFECTIVENESS

CHASE MEDICAL AORTIC ROOT CANNULA

I. General Information

A. Generic Name:	Aortic Root Cannula
B. Trade Name of Device:	Chase Aortic Root Cannula
C. Applicant's Name and Address:	Chase Medical Inc. 1876 Firman Drive. Richardson, Texas 75081
D. Pre-market Notification Number:	Not yet assigned

II. Indications for Use

Chase Medical aortic root cannula is intended for use in conjunction with cardiopulmonary bypass surgery for delivery of cardioplegia solution. The cannula may also be used to aspirate air from the aorta at the conclusion of the bypass procedure.

III. Device Description

During open-heart surgery, the patient's heart is temporarily stopped to allow the surgeon a bloodless, still surface in order to complete the surgical repair. The process of stopping the heart is often achieved by infusing into the heart a solution containing various drugs which act to stop and preserve the heart. This cardioplegia solution is delivered into the heart by way of the aorta and/or into vein grafts. The Chase Aortic Root Cannula is placed into the ascending aorta to deliver cardioplegia solution to the heart. The cannula may be used to aspirate air from the aorta at the conclusion of the bypass procedure.

The Aortic Root Cannula consists of flexible polyvinyl chloride tubing permanently attached to both the polycarbonate inlet and soft, flexible, polyvinyl chloride tip. Tip sizes include 12 gauge and 14 gauge. The inlet fitting is a female luer fitting. The suture ring is soft polyvinyl chloride. The introducer is stainless steel and packaged within the cannula body. The vented Aortic Root Cannula has polyvinyl chloride tubing with a polycarbonate vent line adaptor and vented tip sizes include 12 gauge and 14 gauge.

IV. Device Classification: Class II

V. Safety and Effectiveness

Substantial Equivalence:	The device is substantially equivalent to the DLP, Inc. Aortic Root Cannula K790565.

VI. Other Safety and Effectiveness Data

Materials:	All material are identical to the predicate device.
Sterilization:	Validated 100% Ethylene Oxide sterilization cycle (Overkill Method) SAL 10^{-6}

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Functional Testing

All functional characteristics of the Chase Medical Aortic Root Cannula are non-differentiable as compared with the predicate because both devices have the exact same fit, form, and material composition.

Leak Test Requirements:	No leaks at 10 psi air on Chase device at 4°C and 40°C
Tubing Bond Strength:	Exceeds 10 lb. tensile strength @ 4°C and 40°C
Luer Connections:	Meets ANSI/HIMA MD70.1-1983 for Medical Materials Luer Tape Fittings
Package Integrity:	Tyvek/Polymylar passed burst test per ASTM F1140-88
Shipping & Distribution Testing:	Per National Safe Transit Ass. vibration and drop tests
Accelerated Aging:	Two year shelf life