K971041

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SUMMARY OF SAFETY AND EFFECTIVENESS

CHASE CORONARY OSTIAL PERFUSION CANNULA

I. General Information

A. Generic Name: Coronary Ostial Perfusion Cannula

B. Trade Name of Device: Chase Coronary Ostial Perfusion Cannula

C. Applicant's Name and Address: CHASE MEDICAL, INC., Richardson, TX

D. Pre-market Notification Number: Not assigned

II. Indication for Use:

The Coronary Ostial Perfusion Cannula is intended for use in conjunction with cardiopulmonary bypass surgery for delivery of cardioplegia solutions directly to the coronary arteries.

III. Device Description

These cannulae consist of a basket style tip attached to a malleable stainless steel tube. The cannula terminates with a locking female luer fitting.

IV. Device Classification: Class II device

V. Safety and Effectiveness:

Substantial Equivalence: This device has been shown to be substantially equivalent to the Medtronic/DLP Coronary Ostial Perfusion Cannula.

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}

Functional Testing

All functional characteristics of the Chase Coronary Ostial Perfusion Cannula are non-differentiable as compared with the predicate.

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Leak Test Requirements:	No leaks at 10 psi air on Chase device.
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