

K 964193

APR 16 1997

## SUMMARY OF SAFETY AND EFFECTIVENESS

### CHASE AORTIC ARCH CANNULA

#### I. General Information

- A. Generic Name: Aortic Arch Cannula
- B. Trade Name of Device: CHASE AORTIC ARCH CANNULA
- C. Applicant's Name and Address: CHASE MEDICAL INC. , Richardson, TX
- D. Pre-market Notification Number: Not assigned

#### II. Indication for Use:

The Aortic Arch Cannula is indicated for use for perfusion of the ascending aorta during surgical procedures requiring cardiopulmonary bypass in cases where aortic perfusion is deemed appropriate.

#### III. Device Description

The CHASE Aortic Arch Cannula consists of a curved thin-wall beveled stainless steel tip and a retention collar molded of rigid plastic with an indexing point which indicates the tip orientation when the cannula is in the aorta. The collar has two suture notches for holding the cannula in place. A short length of clear, flexible plastic tubing is attached to the collar. A molded plastic connector of rigid plastic attached to the flexible tube allows connection of the perfusion line to the cannula.

#### IV. Device Classification: Class II device

#### V. Safety and Effectiveness:

Substantial Equivalence: This device is substantially equivalent to the Sarns Aortic Arch Cannula K770429.

#### 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 Medical Aortic Arch Cannula are non-differentiable as compared with the predicate because both devices have the exact same fit, form, and material composition.

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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
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