

K970914

MAY 13 1997

## SUMMARY OF SAFETY AND EFFECTIVENESS

### CHASE AORTIC PERFUSION CANNULA

#### I. General Information

- A. Generic Name: Aortic Perfusion Cannula
- B. Trade Name of Device: CHASE AORTIC 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 Aortic Perfusion Cannula is indicated for use for perfusion of the ascending aorta during surgical procedures requiring cardiopulmonary bypass. Additionally, the Aortic Perfusion Cannula can be used to occlude the ascending aorta as well as deliver cardioplegia solution to and aspirate air from the aorta.

#### III. Device Description

The CHASE Aortic Perfusion Cannula is a three lumen cannula. The primary lumen is the conduit that returns oxygenated blood from the extracorporeal circuit to the ascending aorta. A second lumen allows a balloon to be inflated at the distal tip of the cannula. A third lumen delivers cardioplegia solution through orifices proximal to the balloon.

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

#### V. Safety and Effectiveness:

Substantial Equivalence: This device is substantially equivalent to the combination of Sarns Aortic Arch Cannula (K770429), DLP Aortic Root Cannula (K790565), and an aortic cross clamp.

#### VI. Other Safety and Effectiveness Data:

- Materials: All materials are identical to materials used in similar devices that have similar intended uses.
- Sterilization: Validated 100% Ethylene Oxide sterilization cycle (Overkill Method) SAL  $10^{-6}$

#### Functional Testing

All functional characteristics of the Chase Medical Aortic Perfusion Cannula are non-differentiable as compared with the predicates.