K964199 MAR 19 1997

# SUMMARY OF SAFETY AND EFFECTIVENESS

# CHASE MEDICAL CORONARY SINUS PERFUSION CANNULA

## I. General Information

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| A. Generic Name: | Coronary Sinus Perfusion Cannula |
| B. Trade Name of Device: | Chase Coronary Sinus Perfusion Cannula |
| C. Applicant's Name and Address: | Chase Medical Inc.<br>1876 Firman Drive.<br>Richardson, Texas 75081 |
| D. Pre-market Notification Number: | Not yet assigned |

## II. Indications for Use

The CHASE coronary sinus perfusion cannula is intended for use in perfusing cardioplegia solutions retrograde through the coronary sinus by means of transatrial introduction.

## III. Device Description

The CHASE coronary sinus perfusion cannula is a triple lumen cannula. The main lumen is the delivery conduit for blood or cardioplegia solution. A second lumen is a pressure monitoring line and begins at the tip of the cannula and terminates with a connector for coupling to a pressure monitoring device. A third lumen is used as a means to inject or withdraw air or fluid for the inflation and deflation of a balloon located near the tip of the cannula. The cannula's silicone body is reinforced with wire wound axially along the length of the cannula. A stylet is included to facilitate transatrial placement of the cannula into the coronary sinus. A syringe is included for balloon inflation and deflation.

## IV. Device Classification: Class II

## V. Safety and Effectiveness

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| Substantial Equivalence: | The device is substantially equivalent to the Quest Coronary Sinus Perfusion Cannula K941166. |

## 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 coronary sinus perfusion 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 |
| 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 |