

K964195

MAR 19 1997

SUMMARY OF SAFETY AND EFFECTIVENESS
CHASE TWO STAGE VENOUS RETURN CATHETER

I. General Information

- A. Generic Name: Two Stage Venous Return Catheter
- B. Trade Name of Device: CHASE TWO STAGE VENOUS RETURN CATHETER
- C. Applicant's Name and Address: CHASE MEDICAL INC. , Richardson, TX
- D. Pre-market Notification Number: Not assigned

II. Indication for Use:

The CHASE Two Stage Venous Return Catheter is indicated for single tube venous drainage from the right atrium and vena cava during extracorporeal circulation for open heart surgery.

III. Device Description

The CHASE Two Stage Venous Return Catheter consists of a 27.9 cm (11") length of 51 French flexible plastic tubing attached to a molded, rigid plastic reducer. The reducer has six openings which permit drainage from the right atrium. The reducer is attached to a 7.6 cm (3") length of 36 French flexible plastic tubing, which has a rigid plastic tip. The tip has six openings which allow drainage from the vena cava. The tubing is marked approximately 3 cm and 4.5 cm from the base of the reducer as a reference for determining tip and side hole location during catheter insertion. An obturator is installed in the catheter to minimize blood loss from the reducer during the insertion of the catheter into the right atrium and vena cava.

IV. Device Classification: Class II device

V. Safety and Effectiveness:

Substantial Equivalence: This device is substantially equivalent to the Sarns two stage venous return catheter K770431.

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 Two Stage Venous Return Catheter 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