

K964391

MAY 13 1997

## SUMMARY OF SAFETY AND EFFECTIVENESS

### CHASE LEFT VENT SAFETY VALVE

#### I. General Information

- A. Generic Name: Left Vent Safety Valve
- B. Trade Name of Device: CHASE LEFT VENT SAFETY VALVE
- C. Applicant's Name and Address: CHASE MEDICAL INC. , Richardson, TX
- D. Pre-market Notification Number: Not assigned

#### II. Indication for Use:

The Chase Left Vent Safety Valve is intended to be used during open heart surgery and placed in a vent line to permit flow only away from the heart, prevent buildup of line pressure, and limit line vacuum.

#### III. Device Description

The Left Vent Safety Valve is a three function assembly that is positioned in the vent line and includes a check valve which permits flow only away from the heart. A second vent valve is located downstream of the check valve to prevent buildup of drain line pressure. A third inwardly directed umbrella valve limits line vacuum intensity.

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

#### V. Safety and Effectiveness:

Substantial Equivalence: This device is substantially equivalent to the C.R. Bard overpressure safety valve, (K820297).

#### 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 Left Vent Safety Valve 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**

**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**