

K904200

APR 16 1997

# 510K Summary

## Chase Medical Multiple Perfusion Set

### I. General Information

- A. Generic Name: Multiple Perfusion Set
- B. Trade Name of Device: Chase Multiple Perfusion Set
- C. Applicant's Name and Address: Chase Medical Inc.  
1876 Firman Drive.  
Richardson, Texas 75081
- D. Pre-market Notification Number: Not yet assigned

### II. Indications for Use

Chase Medical multiple perfusion sets are intended for use in conjunction with cardiopulmonary bypass surgery for simultaneous perfusion of the aortic root and 3 or 4 vein grafts.

### III. Device Description

During open-heart surgery, the patient's heart is temporarily stopped to allow the surgeon a bloodless, still surface in order to complete the surgical repair. The process of stopping the heart is often achieved by infusing into the heart a solution containing various drugs which act to stop and preserve the heart. This cardioplegia solution is delivered into the heart by way of the aorta and/or into vein grafts. The multiple perfusion set allows the simultaneous perfusion of cardioplegia into the aortic root and vein grafts.

### IV. Device Classification: Class II

### V. Safety and Effectiveness

Substantial Equivalence: The device is substantially equivalent to the DLP, Inc. Multiple Perfusion Set # K791498.

### 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 multiple perfusion set are non-differentiable as compared with the predicate because both devices have the exact same fit, form, and material composition.

## SUMMARY OF SAFETY AND EFFECTIVENESS

<b>Leak Test Requirements:</b>	<b>No leaks at 10 psi air on Chase device at 4°C and 40°C</b>
<b>Tubing Bond Strength:</b>	<b>Exceeds 10 lb. tensile strength @ 4°C and 40°C</b>
<b>Luer Connections:</b>	<b>Meets ANSI/HIMA MD70.1-1983 for Medical Materials Luer Tape Fittings</b>
<b>Package Integrity:</b>	<b>Tyvek/Polymylar passed burst test per ASTM F1140-88</b>
<b>Shipping &amp; Distribution Testing:</b>	<b>Per National Safe Transit Ass. vibration and drop tests</b>
<b>Accelerated Aging:</b>	<b>Two year shelf life</b>