JAN 31 1997

K964340

SUMMARY OF SAFETY AND EFFECTIVENESS

CHASE VESSEL OCCLUDER

I. General Information

A. Generic Name: Vessel Occluder

B. Trade Name of Device: CHASE VESSEL OCCLUDER

C. Applicant's Name and Address: CHASE MEDICAL INC. , Richardson, TX

D. Pre-market Notification Number: Not assigned

II. Indication for Use:

The Vessel Occluder is intended to be used to internally occlude blood vessels during anastomosis.

III. Device Description

The Vessel Occluder is composed of two silicone rubber bulbs on the distal ends of a flexible shaft. A tab on a tether is attached to the midpoint of the flexible shaft forming a "T" configuration. Vessel Occluders are useful in coronary artery bypass procedures to create a bloodless field at the anastomosis. The occluder bulbs are inserted proximally and distally through the vessel opening. The occluder bulbs allow a dry field to be maintained during the anastomosis of bypass graft.

IV. Device Classification: Class II device

V. Safety and Effectiveness:

Substantial Equivalence: This device has been shown to be substantially equivalent to the Bio-Vascular "Flo-Rester" vessel occluder (K883696).

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 Vessel Occluder are non-differentiable as compared with the predicate because both devices have the exact same fit, form, and material composition.

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Bond Strength:	Exceeds 0.4 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 Assoc. Vibration and drop tests
Accelerated Aging:	Five year shelf life