K972993

MAR 31 1998

August 11, 1997

Food and Drug Administration
Center for Device and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

**Re: 510(k) Summary**

**Attention**: Document Control Clerk

This document is to notify you of the intention of Chase Medical Inc. to manufacture and market the following device.

**Classification Name**: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

**Common / Usual Name**: Femoral Access Cannulation Set

**Proprietary Name**: CHASE FEMORAL ACCESS CANNULATION SET

**Establishment Registration Number**: 9028011

**Classification**: Femoral Access Cannulation Sets are reviewed by the FDA Cardiovascular (CV) Classification Panel. The Product Classification Code and number for the predicate device and this device is 74DWF. According to the classification code, this is a class two device.

**Performance Standards**: None

**Manufacturing Site**: 1876 Firman Dr. Richardson, TX 75081

**Sterilization Site**: Steritec Inc. , Athens TX

**Intended Use**:

The Chase Medical Femoral Access Cannulation Set is intended for use in situations which require rapid femoral venous and arterial access for short term cardiopulmonary bypass. Venous and arterial access is left to the discretion of the physician.

**Substantial Equivalence:**
RMI has marketed a Femoral Access Cannulation Set (K891576) worldwide for 6 years. **The CHASE Femoral Access Cannulation Set is an *exact duplicate* of the RMI Femoral Access Cannulation Set, model number FEM-020.**

**BASIS**
The CHASE device and the RMI device have **identical** physical form, material composition and functional characteristics. Each component is supplied by the **EXACT SAME VENDOR (Angeion Corporation, Plymouth, MN) WITH *IDENTICAL* SPECIFICATIONS**. Section 2 contains a Substantial Equivalence Chart.

**STERILIZATION**
Sterilization of both catheters is conducted using 100% EtO. Section 7 contains Chase Medical's sterilization information.

**PERFORMANCE**
The performance characteristics of the CHASE catheters compared with the RMI device are non-differentiable. **This can be expected considering that the two devices are the exact same product**. Please see Section 6.

**BIOCOMPATIBILITY**
All materials used in the CHASE device are identical to those used in the predicate device. Please see section 5.

**PACKAGING**
Both devices are packaged in Tyvek / Polymylar pouches. Packaging integrity for the CHASE device is validated **after** packaged samples are subjected to sterilization, simulated transportation, and two year accelerated heat aging. The CHASE device will be labeled with a two year expiration date. Please see Section 6.

**LABELING AND ASSEMBLY DRAWING**
All proposed labeling and assembly drawings can be found in Section 3.

In accordance with requirements of the final rule for summaries addressed by the SMDA 1990, Section 8 contains a summary of the safety and effectiveness information upon which the substantial equivalence is based.

If you have any questions pertaining to this submission, please contact me at 972-783-0644.

Sincerely,

Bert Davis
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Bert Davis
President
Chase Medical, Inc.
1876 Firman Drive
Richardson, TX 75081

MAR 31 1998

Re: K972993
Chase Femoral Access Cannulation Set
Regulatory Class: II (Two)
Product Code: DWF
Dated: December 23, 1997
Received: December 31, 1997

Dear Mr. Davis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html."

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K972993

Device Name: Chase Femoral Access Cannulation Set

Indications For Use:

CHASE MEDICAL INC.

FEMORAL ACCESS CANNULATION SET

Intended Use:

The Chase Medical Femoral Access Cannulation Set is intended for use in situations which require rapid femoral venous and arterial access for short term cardiopulmonary bypass. Venous and arterial access is left to the discretion of the physician.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972993

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)