K971023

SUMMARY OF SAFETY AND EFFECTIVENESS

CHASE THORACIC CATHETER

I. General Information

A. Generic Name: Thoracic Catheter SEP - 8 1997

B. Trade Name of Device: Chase Thoracic 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 Thoracic Catheter is indicated for use during and after open-heart surgery to drain fluid from the pericardium.

III. Device Description

The Chase Thoracic Catheter is a polyvinyl chloride tube with precut holes at the distal tip.

IV. Device Classification: Class I device

V. Safety and Effectiveness:

Substantial Equivalence: This device is substantially equivalent to the Sherwood Medical Thoracic Catheter (K760351).

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 Thoracic 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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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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP - 8 1997

Mr. Bert Davis
Chase Medical
1876 Firman Drive
Richardson, Texas 75081

Re: K971023
Chase Thoracic Catheter
Regulatory Class: II (two)
Product Code: 74 DWF
Dated: June 30, 1997
Received: June 30, 1997

Dear Mr. Davis:

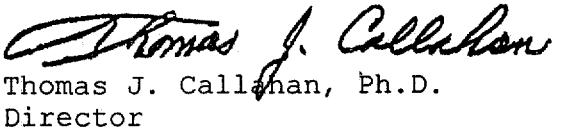
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4639. 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

CHASE MEDICAL, INC.

THORACIC CATHETER

Intended Use:

The Thoracic Catheter is indicated for use during and after open-heart surgery to drain fluid from the pericardium.

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971023