

K971013

SUMMARY OF SAFETY AND EFFECTIVENESS

CHASE TEMPERATURE PROBE

I. General Information

OCT 28 1997

- A. Generic Name: Temperature Probe
- B. Trade Name of Device: Chase Temperature Probe
- C. Applicant's Name and Address: CHASE MEDICAL INC. , Richardson, TX
- D. Pre-market Notification Number: Not assigned

II. Indication for Use:

The Temperature Probe is indicated for use during open-heart surgery to monitor myocardial temperature.

III. Device Description

The Chase Temperature Probe consist of a 15mm stainless steel needle connected to 8 ft. of cable with a dual prong plug.

IV. Device Classification: Class I device

V. Safety and Effectiveness:

Substantial Equivalence: This device is substantially equivalent to the Webster Labs Temperature Probe (K813271).

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 Temperature Probe are non-differentiable as compared with the predicate because both devices have similar fit, form, and function.

SUMMARY OF SAFETY AND EFFECTIVENESS

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 28 1997

Re: K971013
Chase Temperature Probe
Regulatory Class: II (Two)
Product Code: DTN
Dated: August 25, 1997
Received: August 25, 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.

Page 2 - Mr. Bert Davis

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): K971013

CHASE MEDICAL, INC.

TEMPERATURE PROBE

Description:

Clinical:

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 solution is often cooled prior to infusion into the heart. The cooled solution lowers the temperature of the heart. The Chase Temperature Probe monitors the temperature of the heart.

Product:

The Chase Temperature Probe consist of a 15mm, .032 O.D. stainless steel needle. The needle is attached to a cable support and eight feet of insulated twin lead cable. The cable ends in a dual prong connector plug.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ben G. Sampson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K971013

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)