K974568

SUMMARY OF SAFETY AND EFFECTIVENESS

JAN - 6 1998

CHASE ANASTOMOSIS VISUALIZATION DEVICE

I. General Information

A. Generic Name: Anastomosis Visualization Device

B. Trade Name of Device: CHASE Anastomosis Visualization Device

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

D. Pre-market Notification Number: Not assigned

II. Indication for Use:

The Chase Anastomosis Visualization Device is indicated for use during procedures wherein clearing of a wound or surgical site, for enhanced visibility, must be maintained by non-contact means.

III. Device Description

The Chase Anastomosis Visualization Device consists of a malleable wand, a 0.2 micron filter, and a sterile fluid inlet line. The overall length of the wand is approximately 10.125 inches in length. The stainless steel wire is completely embedded within the wall along its length for the purpose of maintaining a user chosen shape. The distal tip is designed to provide a fan-shaped irreigation mist pattern. The remaining proximal length of the wand is the regulated gas inlet which consists of a 0.2 micron medical grade in-line bacterial filter made of a hydrophobic membrane and a 1/4 inch tubing connecter. A 1/4 inch PVC tube which connects the in-line filter to the regulated gas source. A fluid inlet line extends from a point near the proximal end of the malleable section of the wand and terminates in a female luer-lock adaptor for conneciton to a standard fluid administration set which provides for flow control and on-off capacity

IV. Device Classification: Class II device

V. Safety and Effectiveness:

Substantial Equivalence: This device is substantially equivalent to the RMI Surgical Site Visualization Wand.

VI. Other Safety and Effectiveness Data:

Materials: All material are identical to the predicate device.
Sterilization: Validated 100% Ethylene Oxide sterilization cycle (Overkill Method)
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Functional Testing

All functional characteristics of the Chase Medical Anastomosis Visualization Device are non-differentiable as compared with the predicate.

Leak Test Requirements:	No leaks at 10 psi air on Chase device
Tubing Bond Strength:	Exceeds 10 lb. tensile strength
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 20850

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

JAN - 6 1998

Re: K974568
Trade Name: Chase Anastomosis Visualization Device
Regulatory Class: II
Product Code: FMQ
Dated: November 24, 1997
Received: December 5, 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) 594-4618. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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CHASE MEDICAL INC.

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(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 Dental, Infection Control,
and General Hospital Devices
510(k) Number K974568

Prescription Use ✓ OR Over-The-Counter Use _____

(Optional Format 1-2-96)