K973273

XOMED®

SEP 29 1997

510(k) Summary

Xomed T-Stent

1.0 Date Prepared K _____
August 29, 1997

2.0 Submitter (Contact)
Debra B. Cortner
Xomed Surgical Products
Jacksonville, FL
(904) 279-7532

3.0 Device Name
Proprietary Name: T-Stent
Common Name(s): Sinus stent, frontal sinus drain tube
Classification Name: Sinus Catheter

4.0 Device Classification

Sinus Catheter KAM Procode 77 Class I; 21 CFR 874. Tier II

Device Description
The T-Stent is a one-piece radiopaque C-Flex thermoplastic elastomer drainage tube with T-shaped flanges at the proximal end for positioning and retention in the prepared sinus cavity.

6743 Southpoint Dr. N., Jacksonville, Florida 32216-0980 • 904-296-9600 Customer Service 1-800-874-5797

XOMED®

6.0 Intended Use

This device is intended for use as a postoperative stent to maintain an opening to the frontal sinus during the first 7 to 14 days following sinus surgical procedures. The self-retaining stent provides for the ventilation and drainage of fluids from the frontal sinus and helps prevent obstruction by adhesions when used alone or with other nasal stents or packs.

7.0 Substantial Equivalence

The T-Stent described in this notification has the same intended use as the predicate Rains stent, and the same technological characteristics as other sinus stents currently on the market, and does not raise any new issues of safety or effectiveness.

6743 Southpoint Dr. N., Jacksonville, Florida 32216-0980 • 904-296-9600 Customer Service 1-800-874-5797

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 1997

Debra B. Cortner
Senior Regulatory Affairs and Quality System Specialist
Xomed Surgical Products, Inc.
6743 Southpoint Drive North
Jacksonville, FL 32216

Re: K973273
Xomed Frontal Sinus T-Stent
Dated: August 29, 1997
Received: September 2, 1997
Regulatory class: Unclassified
Procode: 77 KAM

Dear Ms. Cortner:

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) 594-4613. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973273

Device Name: T-Stent

Indications for Use:

This device is intended for use as a postoperative stent to maintain an opening to the frontal sinus during the first 7 to 14 days following sinus surgical procedures. The self-retaining stent provides for the ventilation and drainage of fluids from the frontal sinus and helps prevent obstruction by adhesions when used alone or with other nasal stents or packs

.Indications: Any sinus surgery requiring the placement of a drainage stent for the frontal sinus.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ Or Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Bergman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973273