

FEB 8 2000

K994262

510(k) Summary

1.0 Date Prepared

December 16, 1999

2.0 Submitter (Contact)

Martin D. Sargent
Medtronic Xomed, Inc
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name: Frontal Sinus Trephination Cannula
Common Name(s): Irrigation Cannula
Classification Name(s): Introduction/Drainage Catheter and Accessories

5.0 Device Classification

Sinus Trephine, Sinus Irrigation:
Procode 77KBF Class I 21 CFR 874.4420
Irrigation Cannula:
Procode 79GBX Class I 21 CFR 878.4200

6.0 Device Description

The device consists of a cannula and an occlusion plug.

7.0 Intended Use

The Frontal Sinus Trephination Cannula is indicated for patients with sinus disease that require frontal sinus irrigation or repeated frontal sinus irrigation for up to thirty days.

8.0 Substantial Equivalence

The Frontal Sinus Irrigation Cannula is substantially equivalent to the Medtronic Xomed Frontal Sinus Mini-Trephine Set irrigation cannula.

The short-term indwelling aspect of the device is substantially equivalent in intended use to introduction/drainage catheters as defined in 21 CFR 878.4200 which provide short-term access to body cavities. Predicates include common peritoneal catheters and chest drainage tubes including the Vansonenberg Chest Drainage Tubes as described in K925176.

The occlusion plug provided to close the cannula lumen between irrigation procedures is substantially equivalent in design and intended use to the Catheter Plug marketed by Bard Medical.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Martin D. Sargent
Senior Regulatory Affairs Specialist
Xomed, Inc.
6743 Southpoint Drive, North
Jacksonville, FL 32216

Re: K994262
Trade Name: Frontal Sinus Trephination Cannula
Regulatory Class: Unclassified
Product Code: 77KAM
Dated: December 16, 1999
Received: December 17, 1999

Dear Mr. Sargent:

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 legally marketed predicate 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.

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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,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Frontal Sinus Trephination Cannula

Indications for Use:

The Frontal Sinus Trephination Cannula is indicated for patients with sinus disease that require frontal sinus irrigation or repeated frontal sinus irrigation for up to thirty days.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Or

Over-the-Counter Use _____

(Optional Format 1-2-96)

Karen S. Beltrami
(D: _____)

Director, Office of Medical Devices

510(k) Number 2994262