X. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Date Prepared

August 3, 1998

2.0 Submitter (Contact)

Roy Berens, Manager Regulatory Affairs
Xomed Surgical Products
Jacksonville, FL 32216
Telephone: 904-296-6454
Fax: 904-281-1057
e-mail:rberens@xomed.com

3.0 Device Name

Proprietary Name: Xomed MeroGel™ Nasal Dressing and Sinus Stent

Common Name(s): Absorbent Intranasal Splint
Absorbent Intranasal Packing Material
Non-Woven Surgical Packing
Non-Woven Wound Dressing
Non-Woven Compress

Classification Name: Intranasal splint and/or Non-Woven Wound Dressing

4.0 Device Classification

Intranasal Splint	ProCode 77LYA	Class I ; 21 CFR 874.4780 (proposed)
	or	
Wound Dressing	ProCode 79MGQ	Class I ; 21 CRF 878.4022
	or	
Wound Dressing	ProCode 79MGP	Class II ; 21 CRF 878.4012

5.0 Device Description

Xomed MeroGel™ Nasal Dressing and Sinus Stent is a biomaterial composed of HYAFF®, an ester of hyaluronic acid, a natural occurring constituent of the extracellular matrix. Due to its absorption properties, MeroGel™ may be used to help control minimal bleeding. In contact with body fluids, it changes into viscous and transparent gel, conforming to mucosal surfaces and eventually dissolves or may be irrigated from the cavity.

6.0 Intended Use

MeroGel™ Nasal Dressing and Sinus Stent is intended for use in the nasal/sinus cavities as a space-occupying dressing and/or stent, to separate mucosal surfaces and to help control minimal bleeding following surgery.

7.0 Substantial Equivalence

Xomed markets both Merocel® Sinus-Pak™ and Merocel® Standard Nasal Dressing for use in nasal/sinus cavities to control bleeding and/or aid in the prevention of adhesions after surgery. These predicate devices are indicated for nasal/sinus surgery and/or trauma. Xomed MeroGel™ Nasal Dressing and Sinus Stent is substantially equivalent to these predicate products in that it has a similar intended use and indications. The subject and predicate devices are made from materials which have demonstrated satisfactory biocompatibility, are highly absorbent for collecting postop fluids, and are sterile single use.

The difference are that the Xomed MeroGel™ Nasal Dressing and Sinus Stent changes from its original form of a white fibrous material with a physical appearance similar to spun cotton to a gelatinous mass whereas the predicate devices do not dissolve or form a gelatinous mass. Xomed MeroGel™ Nasal Dressing and Sinus Stent can be removed via gentle irrigation whereas the predicate devices require manual removal by moistening and extracting engorged sponge with forceps.

In conclusion, Xomed MeroGel™ Nasal Dressing and Sinus Stent has the same intended use as the predicate devices and differs only in the material which has been shown as biocompatible, as based on the data in the submission raises no new issue of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 1999

Roy Berens
Manager, Quality Systems Regulations
Xomed® Inc.
6743 Southpoint Dr. N.
Jacksonville, FL 32216-0980

Re: K982731
MeroGel™ Nasal Dressing and Sinus Stent
Dated: January 11, 1999
Received: January 13, 1999
Regulatory class: I
21 CFR 874.4100/Procode: 77 EMX

Dear Mr. Berens:

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.

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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Intended Use Statement

510(k) Number (if known): K982732

Device Name: MeroGel ™ Nasal Dressing and Sinus Stent

Indications for Use: Xomed MeroGel™ Nasal Dressing and Sinus Stent is intended for use in the nasal/sinus cavities as a space occupying dressing and/or stent, to separate mucosal surfaces and help control minimal bleeding following surgery.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982731