DEC - 9 1999

510(k) Summary

K99 3112

1.0 Date Prepared

September 16, 1999

2.0 Submitter (Contact)

Martin D. Sargent

Xomed Surgical Products

Jacksonville, FL

(904) 279-7586

3.0 Device Name

Proprietary Name:	Xomed ENT RF System
Common Name(s):	Electrosurgical system
Classification Name(s):	Device, Electrosurgical, Cutting & Coagulation & Accessories

5.0 Device Classification

Device, Electrosurgical, Cutting & Coagulation & Accessories:
Procode 97GEI Class II 21 CFR 878.4400

6.0 Device Description

The Xomed ENT RF System consists of a radio frequency electrosurgical generator with a footswitch and/or fingerswitch to activate the generator RF output, various scissors, forceps, and probe electrosurgical instruments, and accessories including electrical cables to attach various electrosurgical instruments.

The system may be provided with an RF output current indicator, and a built-in peristaltic pump and associated footswitch for fluid irrigation.

7.0 Intended Use

The Xomed ENT RF system is for use by qualified surgeons familiar with radio-frequency electrosurgery techniques. The system produces monopolar and bipolar cutting and coagulation, and may provide fluid irrigation.

Indications in general surgery are for cutting, removal, and coagulation of tissues.

Indications in otorhinolaryngology (ENT) are for cutting, removal, and coagulation of tissues and for the destruction of tissue by thermal ablation in ENT procedures including, but not limited to snoring procedures, submucosal palatal and turbinate shrinkage, and traditional uvulopalatoplasty.

8.0 Substantial Equivalence

The Xomed ENT RF system is substantially equivalent to the Surgitron IEC marketed by Ellman (K990146 and K980177) in its intended use, materials, and overall design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 1999

Mr. Martin D. Sargent
Senior Regulatory Affairs Specialist
Xomed Surgical Products
6743 Southpoint Drive North
Jacksonville, Florida 32216

Re: K993112
Trade Name: Xomed ENT RF System
Regulatory Class: II
Product Code: GEI
Dated: September 16, 1999
Received: September 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 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) 594-4595. 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,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 99 3112
Device Name: Xomed ENT RF System
Indications for Use:

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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 General Restorative Devices
510(k) Number K993112

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

(Optional Format 1-2-96)