K982594

AUG 27 1998

XOMED

K 982594

510(k) Summary of Safety and Effectiveness

1.0 Date Prepared
July 23, 1998

2.0 Submitter (Contact)
Debra B. Cortner
Xomed Surgical Products
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name:	Endo-Scrub/Endo-Scrub 2 (Previously known as ScopeScrubber per K902683/A)
Common Name(s):	Suction/Irrigation device
Classification Names:	Rigid sinus endoscopes (nasopharyngoscopes) and accessories

4.0 Device Classification

Rigid sinus endoscopes and accessories
Procode EOB Class II; 21CFR 874.4760

000065

5.0 Performance Standards

No performance standards have been adopted under Section 514 of the Act . This device will be tested to ensure compliance with the following voluntary standards:

IEC 60601-1-1: 1988 Medical Electrical Equipment - Part 1: General Safety Requirements (Amendment 1:1991; Amendment 2:1995)

IEC 60601-1-2: 1993 Medical Electrical Equipment - Part 1: General Safety Requirements 2. Collateral Standard: Electromagnetic Compatibility Requirements and Tests

6.0 Device Description

The Endo-Scrub 2 Pump is an AC powered microprocessor controlled pump with adjustable irrigation and aspiration cycles. Pump action initiated by depression of the foot control or optional clip-on sheath switch results in a "scrub cycle". The Endo-Scrub 2 Sheath consists of an anodized aluminum sheath attached to an ABS handle with a Luer connector for irrigation tubing.

7.0 Intended Use

The Endo-Scrub 2 is intended to clear accumulated debris from the inserted end of the scope without removing the scope from the surgical site, maintaining visualization during the procedures. It is indicated for use with mechanical endoscopic sinus instruments and with fiber optic lasers in endoscopic nasal and sinus surgery

8.0 Comparison of Characteristics to Substantial Equivalence Predicate

The Endo-Scrub 2 described is otherwise identical to the currently marketed Xomed Endo-Scrub (K902683/A) in general intended use, as well as in general technical characteristics and does not present new issues of safety or effectiveness.

Debra B. Cortner
Sr. Regulatory Affairs and Quality System Specialist

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 1998

Debra B. Cortner
Senior Regulatory Affairs
and Quality System Specialist
Xomed Surgical Products
6743 Southpoint Dr. N.
Jacksonville, FL 32216-0980

Re: K982594
Endo-Scrub/Endo-Scrub 2
Dated: July 23, 1998
Received: July 24, 1998
Regulatory class: II
21 CFR 874.4760/Procode: 77 EOB

Dear Mr. 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 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,

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): ~~K902683/A~~ K982594
Device Name: Endo-Scrub 2
Indications for Use:

The Endo-Scrub 2 is intended to clear the end of a rigid rod endoscope, in order to maintain good visualization of endoscopic procedures without having to remove the scope from the surgical site.

The device is indicated for use during routine diagnostic procedures and during endoscopic sinus surgery with standard mechanical instruments and lasers.

(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)

revised 3/97

David C. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982594