XOMED®

OCT 21 1998

K983224

510k Summary
XPS Drill System

1.0 Date Prepared

September 10, 1998

2.0 Submitter (Contact)

David Timlin
Xomed Surgical Products
Jacksonville, FL
(904) 279-7532

3.0 Device Name

Proprietary Name:	XPS Drill System
Common Name:	Electric Surgical Drill System
Classification Name:	ENT electric or pneumatic surgical drill

4.0 Device Classification

Currently marketed products of this type have been classified by the Ear, Nose and Throat Panel as follows:

ENT electric or pneumatic surgical drill	77ERL	Class II	874.4250
Surgical Instrument Motors and accessories	79GEY	Class I*	878.4820

* exempted from premarket notification.

5.0 Device Description

The XPS Drill System is made up of a console, electric motor, exchangable handpieces, foot pedal and accessories as described below. It has the ability to operate one handpiece and incorporates irrigation capability. The handpiece speed range is 0 - 90,000 RPM and the stall torque is 3.5 oz-in.
NOTE: There is no software involved with the operation of this device.

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

Revised 10/13/98

6.0 Intended Use

The XPS Drill System is primarily intended for the controlled incision or removal of bone in the ear, nose, throat and other areas of the head and neck.

7.0 Substantial Equivalence

The new XPS Drill System is the same drill system that was previously cleared by K904850. Xomed now intends to market this system for ENT and Head and Neck surgery. In so doing, we have made some minor changes to the labeling, i.e. the instruction manual and the console. None of these changes are significant and are typical of any ENT drill. As an ENT drill, the XPS Drill System is also substantially equivalent to the MPS Powerforma currently marketed by Xomed (K960853). Information from the MPS Powerforma manual was used in modifying the Micro Motors manual for the proposed XPS Drill.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

David M. Timlin
Manager, Regulatory Affairs
Xomed Surgical Products, Inc.
6743 Southpoint Drive North
Jacksonville, FL 32216

Re: K983224
Xomed XPS Drill System
Dated: September 10, 1998
Received: September 14, 1998
Regulatory class: II
21 CFR 874.4250/Procode: 77 ERL

Dear Mr. Timlin:

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

Revised 10/13/98

510(k) Number (if known): K983224
Device Name: XPS Drill System
Indications for Use:

The XPS Drill System is intended for the controlled incision or removal of bone in the ear, nose, throat and other areas of the head and neck.

(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. Nagurn
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983224