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XOMED®

Revised October 1, 1998

~~K983205~~ K983025

510(k) Summary

1.0 Date Prepared

August 28, 1998

2.0 Submitter (Contact)

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

3.0 Device Name

Proprietary Name:	Xomed FeatherTouch XPS Power Rasp Attachment,
Common Name(s):	Drill attachment, oscillating attachment
Classification Name:	ENT surgical drill and Surgical instrument motor accessories

4.0 Device Classification

ENT Drill Procode 77ERL Class II ; 21 CFR 874.4250 Tier 1
Surgical Motors and Accessories Procode 79GEY Class I ; 21 CFR 878.4820 Tier 1 878.4820 is now exempt from 510(k) notification.
Note: Bur rasp /blade tips to be used with the Power Rasp Attachment are exempted from notification by 21 CFR 874.4140 Ear, Nose and Throat Bur. Surgical motors and accessories are exempt from 510(k) under 21 CFR 878.4820.

5.0 Device Description

The XPS Power Attachment is a mechanical attachment to the collet drive of the XPS Straight Shot handpiece that converts rotary motion to oscillating motion (forward and backward) to drive the cutting bit.

6.0 Intended Use

The Power Rasp is intended for use as an accessory to the XPS Straight Shot handpiece The Xomed XPS StraightShot Microdebrider System is intended for the cutting and removal of soft and hard tissue or bone in otorhinolaryngology, head and neck, and orthopedic surgery. It is indicated for use in orthopedic surgical procedures where the cutting and removal of soft and hard tissue or bone is needed. These include open spinal surgeries and small and large joint arthroscopic procedures.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Debra B. Cortner
Senior Regulatory Affairs Specialist
Xomed, Inc.
6743 Southpoint Dr. North
Jacksonville, Florida 32216

Re: K983025
Trade Name: Xomed FeatherTouch XPS Power Rasp Attachment
Regulatory Class: II
Product Code: HRX
Dated: August 28, 1998
Received: August 31, 1998

Dear Ms. 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 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K983025:
Device Name: FeatherTouch Power Rasp Attachment
Indications for Use:

The Power Attachment for cutting blades / rasps is indicated for use with the XPS Straight Shot Microdebrider during surgical procedures to operate these various accessories to cut hard and soft tissue or bone in orthopedic and otorhinolaryngology and head and neck surgery. These include open spinal surgeries and small and large joint arthroscopic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983025