JAN 30 1998

K973499

510(k) Summary

1.0 Date Prepared
September 15, 1997

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

3.0 Device Name

Proprietary Name: XPS StraightShot Microdebrider System or TreBay Shaver System (The proposed product tradename has not been finalized and may be changed at a later date)

Common Name(s): Electrical surgical shavers, electrical debriders, drill handpieces and cutting blades and burs

Classification Name: Surgical instrument, AC powered motors and accessories / attachments or Arthroscopes and accessories

5.0 Device Classification

Surgical instrument, AC powered motors and accessories / attachments
Procode 87HWE Class II ; 21 CFR 878.4820 Tier 1

Arthroscopes and accessories
Procode 87HRX Class II ; 21CFR 888.1100 Tier 2

6.0 Device Description

The XPS System remains essentially the same as originally described in K963246. There is a Power Control Unit, a footswitch, reusable handpieces and various interchangeable, disposable burs and blades. The system can operate one or two handpieces (one at a time) with suction and irrigation, depending on the handpiece. Xomed now proposes to market the XPS System for the same intended use in orthopedic surgery, including spinal and small and large joint procedures. In order to best meet the needs of the orthopedic surgeons, we have added to the original system, a larger handpiece and additional blades and burs. Other than the larger motor with additional speed and torque, the principle of operation and Power Control Unit remain essentially the same as described in K963246.

7.0 Intended Use

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. Orthopedic use is now added to the original intended use for otorhinolaryngology and head and neck 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 spinal and small and large joint arthroscopic procedures.

8.0 Substantial Equivalence

All of the predicate devices (Linvatec Apex, Stryker SE5, S&N Dyonics PS3500EP, S&N Dyonics Arthroscopic MicroDiscectomy (AMD) System, Sofamor Danek Tissue Resecting System) have similar designs with equivalent characteristics. Most importantly all of the predicate devices are marketed for arthroscopic orthopedic uses. Information on labeling of the predicate devices was included.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

Mr. David Timlin
Manager, Regulatory Affairs
Xomed, Incorporated
6743 Southpoint Drive, North
Jacksonville, Florida 32216-0980

Re: K973499
Trade Name: XPS StraightShot Microdebrider System or TreBay Shaver System
Regulatory Class: II
Product Code: HRX
Dated: December 1, 1997
Received: December 2, 1997

Dear Mr. Timlin:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 (if known): K973499

Device Name: XPS StraightShot Microdebrider System

Indications for Use:

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 spinal and small and large joint arthroscopic procedures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973499

Prescription Use X
(Per 21 CFR 801.109)

Or Over-the-Counter Use _____

(Optional Format 1-2-96)

revised 3/97