



Revised 8/25/97

510(k) Summary

1.0 Date Prepared
June 27, 1997

SEP - 5 1997

2.0 Submitter (Contact)

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

3.0 Device Name

Proprietary Name: XPS StraightShot Microresector System and/or Sculpture System, and various descriptive tradenames for burs and blades as accessories for the system.)

Common Name(s): Electrical surgical drill, microdebrider, or microresector, handpieces, burs and blades

Classification Name: ENT Surgical Drill

5.0 Device Classification

ENT Surgical Drill Procode: 77 ERL Class II; 21CFR 874.4250 Tier 1
ENT Bur (Blade) Procode: 77 EQJ Class I; 21CFR 874.4140 Tier 1

6.0 Device Description

The XPS microdebrider system is composed of the Power Control unit, a footswitch and a handpiece combined with various accessory blades and burs. The XPS system and replaceable blades and burs are intended for use by health care professionals and are labeled as prescription devices. The disposable blades and burs are provided in styles and sizes to remove the various tissues and bone typically resected in ENT and Head and Neck surgery.

7.0 Intended Use

This device is intended for the cutting and removal of bone and tissues in ENT, otorhinolaryngology / head and neck surgical procedures.

8.0 Substantial Equivalence

This submission is to obtain FDA concurrence that the specific procedures (rhinoplasty and removal of soft tissue during plastic, reconstructive, and/or aesthetic surgery of the head and neck) indicated in the proposed labeling are substantially equivalent to the current broadly stated indications for use. No other modifications or device changes are included.

The use of the XPS System for rhinoplasty is equivalent to the TreBay Microplaner handpiece, cleared via K954715, which is described as having a 4.4 mm cutting bur with a hooded tip and handpiece. Its cleared indications for use included "for removal of bone and tissues in rhinoplasty, for such procedures including nasal dorsum surgery and nasal osteotomy, and surgery for rhinoplasty".

The additional indication proposed for soft tissue removal during plastic, reconstructive, and/or aesthetic surgery of the head and neck is only identifying a specific soft tissue removal that is commonly carried out by the ENT/Head and Neck surgeon. The removal of this tissue is equivalent to the removal of any other soft tissue of the head and neck in that it raises no new issues of safety or effectiveness. In a multi-institutional experience for these indications (article of Becker, et al.), the use of powered cutting blades is found to be safe and effective for removal of such tissue.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 5 1997

David Timlin
Manager, Regulatory Affairs
XOMED Surgical Products
6743 Southpointe Drive, N.
Jacksonville, FL 32216

Re: K972453
XPS Straight Shot Electronic or Pneumatic
Surgical Drill
Dated: June 27, 1997
Received: June 30, 1997
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 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) 594-4613. 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/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): K972453

Device Name: Xomed (Trey) Microdebrider / resector. XPS StraightShot. XPS Sculpture systems and accessory blades and burs

Indications for Use:

This device is intended for the cutting and removal of bone and tissues in ENT, otorhinolaryngology / head and neck surgical procedures.

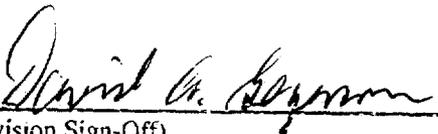
Indications: Any ENT, otorhinolaryngological, or head and neck surgery requiring the incision and removal of bone or tissue, including removal and shaping of bone during rhinoplasty procedures and removal of soft tissue during plastic, reconstructive, and/or athetic surgery of the head and neck.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972453