K041413

JUL 1 2 2004

510(k) Summary

1.0 Date Prepared

May 26, 2004

2.0 Submitter (Contact)

Martin D. Sargent
Regulatory Affairs Manager
Medtronic Xomed
Jacksonville, FL
(904) 279-7586

3.0 Device Name

Proprietary Name:	XPS 3000 System.
Common Name(s):	Electrical surgical shavers, electrical microresectors, mastoid drills, microdrill, ENT drills, handpieces and cutting blades, rasps and burs.
Classification Name(s):	Drill, Surgical, ENT (Electric or pneumatic) including handpiece.

4.0 Device Classification

Classification Name: Drill, Surgical, ENT (Electric or pneumatic) including handpiece

Procode	77ERL	Class II	21 CFR § 874.4250
Procode	77EQJ	Class I	21 CFR § 874.4140

5.0 Device Description

The XPS 3000 system consists of a power control console, footswitches, connection cables, and assorted handpieces to drive various burs, blades, drills, and rasps.

6.0 Indications for Use

The XPS 3000 is intended for the incision and removal of soft and hard tissue or bone in general otorhinolaryngology, head and neck, and otoneurological surgery.

Otology / neurotology indications include mastoidectomy, mastoidotomy, and acoustic neuroma.

Sinus indications include septoplasty, removal of septal spurs, polypectomy, antrostomy, ethmoidectomy/sphenoethmoidectomy, frontal sinus trephination and irrigation, frontal sinus drill out, endoscopic DCR, trans-spheniodal procedures, maxillary sinus polypectomy, circumferential maxillary antrostomy, choanal atresia, sphenoidotomy, and medial, lateral, and posterior frontal sinusotomy.

Nasopharyngeal / laryngeal indications include adenoidectomy, tracheal procedures, laryngeal polypectomy, laryngeal lesion debulking, tonsillectomy, tonsillotomy for obstructive tonsillar disease, removal of endobronchial lesions, and the surgical management of recurrent respiratory papillomatosis (RRP).

Head and neck (ENT) indications include soft tissue shaving, rhinoplasty (narrowing of the bony vault and revision of the bony pyramid), removal and shaping of bone during rhinoplasty procedures, removal of adipose tissue (lipo debridement) in the maxillary and mandibular regions of the face, removal of acoustic neuroma, and incision and removal of soft tissue during plastic, reconstructive, and/or aesthetic surgery.

The XPS 3000 system using the PowerSculpt handpiece and reciprocating cutting blades / rasps is indicated to cut hard and soft tissue or bone in otorhinolaryngology and head and neck surgery.

The XPS 3000 system with reciprocating adapter and suction cannula is intended for the removal of soft tissue and fluid during general surgical procedures including suction lipoplasty for aesthetic body contouring.

The XPS 3000 system is indicated for use in orthopedic surgical procedures where the cutting and removal of soft and hard tissue or bone is required. These include spinal and small and large joint arthroscopic procedures.

An integral pump is provided for irrigation, and a second integral pump may be provided for handpiece cooling.

Characteristic	XPS 3000 Expanded Indications	XPS 3000 (K002224)
Intended Use / Indications for use	Cutting soft tissue and bone (See page 7)	Cutting soft tissue and bone (See page 6)
Magnum / Straightshot Microresector FWD / REV	Default: 6,000 RPM Max: 6,000 RPM	Default: 6,000 RPM Max: 6,000 RPM
Magnum / Straightshot Microresector Oscillation Speed	Default: 3,000 RPM Max: 3,000 RPM	Default: 3,000 RPM Max: 3,000 RPM
Magnum II / M4 Microresector FWD / REV	Default: 6,000 RPM Max: 15,000 RPM	Default: 6,000 RPM Max: 15,000 RPM
Magnum II / M4 Microresector Oscillation Speed	Default: 3,000 RPM Max: 5,000 RPM	Default: 3,000 RPM Max: 5,000 RPM
Steam autoclavable handpieces	Yes	Yes
Blade sizes (O.D.)	2.0 mm - 6mm	2.0 mm - 6mm
Direct patient contacting materials (Burs / Blades)	Stainless Steel and medical polymer	Stainless Steel and medical polymer
Blades / burs biocompatible	Yes	Yes
Perastaltic pumps	2 pumps, 1 for irrigation and 1 optional pump for handpiece cooling	2 pumps, 1 for irrigation and 1 optional pump for handpiece cooling

Table 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2 2004

Medtronic Xomed
c/o Martin D. Sargent
Regulatory Affairs Manager
6743 Southpointe Drive, N.
Jacksonville, Florida 32216-0980

Re: K041413
Trade/Device Name: XPS 300 System
Regulation Number: 21 CFR 874.4140
Regulation Name: Ear, nose and throat electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: May 26, 2004
Received: May 27, 2004

Dear Mr. Sargent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K041413
Device Name: XPS 3000 System
Indications for Use:

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(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 Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K041413