K041985

AUG 1 2 2004

# 510(k) Summary

## 1.0 Date Prepared

June 25, 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 Curved Bur (the tradename has not been finalized at this time) |
| Common Name(s): | ENT bur |
| Classification Name(s): | Ear, nose, and throat bur |

## 4.0 Device Classification

| | | | |
|---|---|---|---|
| Classification Name: | Ear, nose, and throat bur | | |
| Procode: | 77EQJ | Class I | 21 CFR § 874.4140 |

## 5.0 Device Description

The XPS Curved Bur consists of a cutting tip connected to a flexible bur shank which is surrounded by a stationary outer cannula. The flexible shank and cutting tip are rotated by a surgical drill motor.

## 6.0 Indications for Use

The XPS Curved Bur is intended for use in an ear, nose, and throat electric or pneumatic surgical drill for incising or removing bone in the ear, nose, or throat area, and is an accessory to the XPS 3000 System.

## 7.0 Substantial Equivalence

The proposed XPS Curved Bur is substantially equivalent in operating principle, technology, overall design, function, and cutting surface materials to ENT Burs as described in 21 CFR § 874.4140. Risk analysis reveal no new safety or efficacy issues associated with the proposed device.

| **Characteristic** | **ENT Bur (21 CFR § 874.4140)** | **XPS Curved Bur (This submission)** |
|---|---|---|
| Intended Use / Indications for use | Incising or removing bone in the ear, nose, or throat area | Incising or removing bone in the ear, nose, or throat area |
| For use with a surgical drill per 21 CRF § 874.4140 | Yes | Yes |
| Maximum rotational speed | 80,000 RPM | 80,000 RPM |
| Bur guard integrated into design or available as an accessory | Yes | Yes |
| Direct patient contacting materials (Burs / Blades) | Stainless Steel and medical polymer | Stainless Steel, 6/6 nylon thread, and medical polymer |
| Blades / burs biocompatible | Yes | Yes |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 1 2 2004

Medtronic Xomed, Inc.
c/o Mr. Jefffrey D. Rongero
Underwriters Laboratories, Inc.
12 Laboratory Dr.
Research Triangle Park, NC 27709

Re: K041985
Trade/Device Name: XPS Curved Bur
Regulation Number: 21 CFR 874.4140
Regulation Name: ENT Bur
Regulatory Class: Class I
Product Code: 77 EQJ
Dated: July 21, 2004
Received: July 23, 2004

Dear Ms. Rongero:

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

# Indications for Use

**510(k) Number (if known):**
**Device Name:** XPS Curved Bur
**Indications for Use:**

The XPS Curved Bur is intended for use in an ear, nose, and throat electric or pneumatic surgical drill for incising or removing bone in the ear, nose, or throat area, and is an accessory to the XPS 3000 System.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Opnthalmic Ear,
Nose and Throat Devises

510(k) Number K041985

Prescription Use X
(Per 21 CFR 801.109)