MAR 20 2009

K083720

Bien-Air Surgery

510(k) Summary

Date prepared : 3rd. December 2008

Made by :
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Device Name:

Proprietary name: OSSEODUO Shaver and Drill System

Common names:
Electrical microresector, microdebrider, shaver
Shaver blades, cannulae
Electrical surgical drill, ENT drill, straight and angled handpieces, micro-saw handpieces
Burs, saw blades

Classification name:

OSSEODUO Shaver and Drill System:
Drill, surgical, ent (electric or pneumatic) including handpiece
(21 CFR 874.4250, Product code ERL)
Class II

Shaver blades, burs, rasps and saw blades:
Bur, Ear, Nose And Throat
(21 CFR 874.4140, Product code EQJ)
Class I

Applicable 510(k) of predicate devices (substantial equivalence):

Device	Manufacturer	FDA Clearance
XPS 3000 System	Medtronic Xomed Inc.	K041523
Diego powered Dissector and Drill System	Gyrus ENT L.L.	K020594

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Device Description:

The OSSEODUO Shaver and Drill System consists of a control unit, a footswitch, connection cables, a shaver handpiece (also named microdebrider or microresector) to drive various shaver blades, a drill motor and assorted handpieces to drive various burs, drills, rasps and micro saw.

The control unit consists of a closed box with, on its main side, an LCD display screen and various function keys allowing the device to be adjusted according to the planned operation. On the right-hand side of the control unit are the connectors for the shaver handpiece S80 and for the micromotor 80K, while the pedal is connected on the rear panel. A peristaltic pump for irrigation and cooling is mounted on the rear panel which also contains the main power-up switch and the fuse holder.

The shaver handpiece includes a micromotor, a gear set, a coupling system for shaver blades and connections for irrigation and suction. Through the control unit it can operate in oscillating modus (reversing after a user-defined number of turns in each direction) or in continuous CW and CCW rotation. Its made of stainless steel and autoclavable. The shaver handpiece is available in two version: the S80 being the basic model and the S120 with higher rotation speed (up to 12'000 rpm in continuous rotation) and the ability to orient the shaver blade during operation without releasing the chucking mechanism.

The micromotor 80K has an ISO 3964 type E standard coupling which connects to a broad range of different handpieces, such as drill, contra-angle, saw, etc. Through the control unit it can achieve speeds of up to 80'000 rpm. All outer surfaces are made of stainless steel and the motor is autoclavable.

The footswitch allow a smooth progressive and continuous command of the shaver or drill speed. It is IPX8 waterproof.

Accessories:
Shaver blades are round elongated stainless steel cutting instruments, with a small cutting window at the distal tip. At the proximal end a coupling part allow the mounting in the handpiece S80 or S120. The shaver blades have built in ways for irrigation and suction.
They are available in different diameters, with different geometries and different cutting edges. All shaver blades come in sterile packaging (ETO), most are disposable and for single use only.
These accessories are designed to be used with the shaver handpiece S80 or S120 only.

Other accessories for the OSSEODUO System include burs, drills and saw blades, which are available sterile or non-sterile, as well as the irrigation lines to be used with the peristaltic pump of the control unit, which are disposable and sterile packaged.

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Intended use of the Device:

The OSSEODUO is a drill and shaver system that has been designed for drilling and shaping bone and for the resection of soft and hard tissues as part of surgical operations in the areas of otorhinolaryngology, otoneurology, maxillofacial surgery, and head and neck surgery.

The shaver handpiece S80 or S120 is designed for cutting and removal of soft and hard tissue in the fields of:

- Endoscopic sinus surgery (such as ethmoidectomy, polypectomy, septoplasty)
- Endoscopic dacryocystorhinostomy (DCR)
- Nasopharyngeal and laryngeal prodedures (such as adenoidectomy, polypectomy, tonsillectomy)
- Head and neck surgery(such as acoustic-neuroma removal, tumor removal, rhinoplasty, adipose tissue removal, plastic, reconstructive and aesthetic surgery)

The micromotor 80K combines with different drill and micro saw handpieces and is intended for cutting, drilling, shaping and sawing bone as part of various surgical procedures in the areas of ENT and head and neck surgery such as otoneurology, otorhinolaryngology and maxillofacial surgery (facial plastic, reconstructive and aesthetic surgery).

The intended use of the OSSEODUO is substantially equivalent to that of the predicate devices.

Summary of technological characteristics:

Characteristic	**XPS 3000 Expanded Indications**	**Diego Dissector and Drill System**	**OSSEODUO Shaver & Drill System**
Intented Use	Cutting soft tissue and bone	Cutting soft tissue and bone	Cutting soft tissue and bone
Driver configuration	Console with separate footswitch	Console with separate footswitch	Console with separate footswitch
Energy source	Electric	Electric	Electric
Speed Indication	Digital	Digital	Digital
Fonctions	Drill and Microdebrider	Drill and Microdebrider	Drill and Microdebrider
Drill-Fonctions:	From 10'000 rpm to 80'000 rpm Forward and reverse	Up to 44'000 rpm Forward and reverse	From 4000 to **80'000** rpm Forward and reverse
Peristaltic pumps	2 pumps, 1 for irrigation and 1 optional pump for handpiece cooling	1 pump integrated into console for irrigation	1 pump integrated into console for irrigation
Number of Handpieces supported	6: StraightShot Magnum I or II, Powerforma, Powersculpt, Skeeter, Xcalibur drill	4: Diego, Stapes, Viper Drill straight and angled	**Unlimited**: Shaver handpiece S80 or S120, Drill Micromotor 80K with standard ISO 3964 Type E coupling which connects to a number of different handpieces (straight, angled, microsaw, etc).

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Microdebrider Operating Modes	Forward, Reverse, Oscillate	Forward, Reverse, Oscillate	Forward, Reverse, Oscillate
Microdebrider (Microresector) FWD / REV speed	Straightshot M4: From 500 to 12'000 rpm. Default: 6,000 rpm	Diego: up to 15'000 rpm	Handpiece S120: From 400 to 12'000 RPM Default: 12'000 RPM Handpiece S80: From 400 to 8'000 RPM Default: 8'000 RPM
Microdebrider (Microresector) Oscillation Speed	Straighshot M4: From 500 to 5000 RPM Default: 5,000 RPM	Diego: Up to 5000 rpm	Handpiece S80 & S120: From 300 to 5,000 RPM Default: 3,500 RPM
Duty cycle at full load oscillating:	Max 60s on Min 30s off	Max 30s on Min 1 minute 30s off	Max 3 min 30s on, Min 6 min off
Steam autoclavable handpieces	Yes	Yes	Yes
Blade sizes (O.D.)	2.9 mm – 6 mm	2.9 - 4.6mm	3.0 mm – 4.0 mm
Suction Capability (micro-debrider)	Yes suction port in line with shaver blade, diameter 3.4mm	Yes suction port in line with shaver blade	Yes suction port in line with shaver blade, **diameter 3.9mm**
Irrigation Capability	Yes, Irrigation port on the shaver blade.	Yes, Irrigation port on the handpiece	Yes Irrigation port on the handpiece
Direct patient contacting materials (Burs / Blades)	Stainless Steel and medical polymer	Stainless Steel and medical polymer	Stainless Steel and medical polymer
Blades / burs biocompatible	Yes	Yes	Yes

Non clinical performance assessment

The substantial equivalence of the OSSEODUO to the Xomed XPS 3000 with Straightshot M4 and to the Gyrus Diego has been tested with various experiments.
Following trials have been conducted:

- Resection of oyster-flesh mixed with eggshell to simulate the resection of cartilage.
- Resection of scallops flesh
- Aspiration of water

By each trial, following points have been watched: weight of removed tissues, frequency of clogging of the aspiration system.

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These experiments have confirmed that the OSSEODUO system has a similar rate of tissue removal (grams per minute) to the two reference systems. The aspiration of water with the same vacuum system has also shown equivalent results. Pertaining frequency of clogging, the results vary widely randomly from one measure to the other even with the same system so that comparison between systems are difficult.

These experiments have however clearly confirmed that the OSSEODUO system is equivalent in its function and capability to the predicate devices.

Post Market Surveillance

As the OSSEODUO system has been CE-marked and cleared for market in Europe since October 2007, feedback of clinical performance of the OSSEODUO system has been reported by different ENT Surgeons from Italy, Switzerland and China.
Following topics have been addressed by the surgeons
- Cutting performance of the shaver blades compared to competition
- Suction/aspiration capability in shaver mode
- Drilling of bone at 40'000 rpm compared to competition

The different surgeon's reports confirm the effectiveness and safety of the OSSEODUO system

Conclusions

A comparison of technical features, non clinical testing with the predicate systems as well as post market performance feedback demonstrate that the OSSEODUO system is substantially as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2009

Bien Air Surgery SA
c/o Hugues Froidevaux
Quality & Regulatory Affairs Manager
Rue de l'Ouest 2b
Le Noirmont
Switzerland 2340

Re: K083720
Trade/Device Name: OSSEODUO Shaver and Drill System
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, nose, and throat electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: February 3, 2009
Received: February 18, 2009

Dear Mr. Froidevaux:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083720

Indications for Use

510(k) Number (if known): K083720

Device Name: OSSEODUO, Shaver Handpiece S80 and S120, Micromotor 80K

Indications for Use:

The OSSEODUO is a drill and shaver system that has been designed for drilling and shaping bone and for the resection of soft and hard tissues as part of surgical operations in the areas of otorhinolaryngology, otoneurology, maxillofacial surgery, and head and neck surgery.

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X

Prescription Use
(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

510(k) Number K083720