DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Bien-Air Surgery SA
% Mr. Roland Hasler, CEO
Rue de l'Ouest 2b
2340 Le Noirmont
Switzerland

Re: K143492
Trade/Device Name: OSSEOSTAP Microdrill System (Control Unit, Handpiece and Burs)
Regulation Number: 21 CFR 874.4250
Regulation Name: Ear, Nose, and Throat Electric Or Pneumatic Surgical Drill
Regulatory Class: Class II
Product Code: ERL, EQJ
Dated: December 3, 2014
Received: December 8, 2014

Dear Mr. Hasler:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143492

Device Name
OSSEOSTAP Microdrill System

Indications for Use *(Describe)*
The OSSEOSTAP system has been designed for the light drilling of bones as part of surgical operations such as stapedotomy or ossiculoplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Date prepared: December 1, 2014

Submitter:
Bien-Air Surgery SA
Rue de l'Ouest 2b
2340 Le Noirmont Switzerland
Phone: +41 32 953 35 35 Fax: +41 32 953 35 37

Contact person:
Hugues Froidevaux, Quality and Regulatory Affairs Manager
Email: hugues.froidevaux@bienair.com

Device Name:
Proprietary name: OSSEOSTAP Microdrill System
Common names: Electrical surgical drill, ENT drill
Burs

Classification name:
Drill, Surgical, ENT (electric or pneumatic) including handpiece
(21 CFR 874.4250, Product code ERL), Class II

Burs
Bur, Ear, Nose and Throat
(21 CFR 874.4140, Product code EQJ), Class I

Predicate device:
Primary predicate device:

Device	Classification	Manufacturer
Skeeter Ultra-Lite Oto-Tool Drill	874.4250, ERL, Class 2 Drill, Surgical, ENT (electric or pneumatic) including handpiece. Covered by K041523	Medtronic Xomed Inc.

Substantial equivalence is claimed to the skeeter OTO-Tool drill, which is an accessory to the XPS3000 console, which is the subject of K041523.
The description of the Skeeter (from the IFU of Medtronic XPS 3000 system), is as follows:

SKEETER® ULTRA-LITE OTO-TOOL — A slender, lightweight drill handpiece and burs specifically used in middle ear surgical procedures, including stapes footplate procedures. The Skeeter® may be powered from the XPS® 3000 console, XPS® 2000 console, or from a battery powered variable speed foot control.

Bien-Air Surgery SA
Rue de l'Ouest 2b CH-2340 Le Noirmont Phone +41 (0)32 953 35 35 Fax +41 (0)32 953 35 37
Sales & Marketing: Phone +41 (0)32 344 64 40 Fax +41 (0)32 344 64 45 surgery@bienair.com www.bienairsurgery.com

Reference device:

Fisch Drill System	874.4250, ERL, Class 2 Drill, Surgical, ENT (electric or pneumatic) including handpiece	Jedmed Instrument Co. (original applicant, K792159)

Device Description:

The OSSEOSTAP Microdrill System consists of a foot control unit and a handpiece, with an integrated micromotor, to drive various burs.
The battery-operated foot control unit, connected via the drill cable, regulates the rotation speed.

Intended use of the Device:

The OSSEOSTAP system has been designed for use by medical professionals for the light drilling of bone as part of surgical ENT otology procedures, such as stapedotomy or ossiculoplasty.

Summary of technological characteristics:

Characteristic	**Skeeter Ultra-Lite Oto-Tool Drill Medtronic Xomed Inc.** (Accessory of K041523)	**Fisch Drill System Jedmed Instrument Co.** (K792159)	**OSSEOSTAP Microdrill Bien-Air Surgery SA**
Intended Use	Light drilling of bone	Drilling, cutting and shaping bone	Light drilling of bone
Control Unit	Foot pedal	Foot pedal	Foot pedal
Energy source	Electrical (batteries)	Electrical (AC)	Electrical (batteries)
Rotation speed	Max. 12,000 rpm	Max. 40,000 rpm	Max. 12,000 rpm
Steam autoclavable handpieces	Yes	Yes	Yes
Direct patient contact materials	Stainless steel	Stainless steel	Stainless steel
Burs biocompatible	Yes	n.a.	Yes

The characteristics of the OSSEOSTAP are comparable to those of the predicate device.

The Fisch, Skeeter and OSSEOSTAP drills are all indicated for use in otology (e.g. middle ear) surgical procedures. The maximum rotation speed of the Fisch drill is higher because it can be used for a broader range of indications (including mastoid and plastic surgery).

Performance Data (non-clinical tests):

The OSSEOSTAP was bench tested in parallel with the predicate device Skeeter to confirm that handling, cutting performance and noise level were at least as good.
The OSSEOSTAP bur resistance has been evaluated on the basis of repeated running, traction tests and repeated sterilization cycles.
Functionality of the OSSOSTAP handpiece after multiple reprocessing has been confirmed with a cycle test.

Cleaning validation of the OSSEOSTAP handpiece has been validated in an external lab using proteins as marker. Moist heat sterilization has been validated based on lab validation of 2 related devices sharing similar components but featuring more complex geometry.
For the dedicated reusable burs, both the cleaning and the steam sterilization have been validated by an external lab.

Biocompatibility of the OSSEOSTAP was evaluated according to ISO 10993-1. The curved tip of the handpiece as well as the burs are in direct contact with bone or tissue for a limited duration. Materials are stainless steel for the handpiece, stainless steel and diamond, respectively carbide for the burs.

The software that controls the micro-controller in the OSSEOSTAP footcontrol has been classified as minor level of concern. All validation documents are available.

The electrical safety of the OSSEOSTAP System has been certified through the standards IEC 60601-1 3rd edition, which includes an EMC certification according to IEC 60601-1-2.

No clinical performance data was deemed necessary for this 510(k)

Substantial Equivalence:

The OSSEOSTAP Microdrill System has the same intended use and operating principle as the predicate device. Through comparison of technical and performance characteristics, the OSSEOSTAP is considered to be as safe and effective as the predicate device, and therefore, substantially equivalent.