June 22, 2018

Bien-Air Surgery SA
% Belia Juarez
Regulatory Project Manager
Ken Block Consulting
1201 Richardson Drive, Suite 160
Richardson, Texas 75080

Re: K173066
Trade/Device Name: OSSEODUO Shaver and Drill System
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric cranial drill motor
Regulatory Class: Class II
Product Code: HBC, HBE
Dated: May 24, 2018
Received: May 25, 2018

Dear Belia Juarez:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173066

Device Name
OSSEODUO Shaver and Drill System

Indications for Use *(Describe)*
The OSSEODUO system is intended for shaping bones in spine and cranium surgical operation. Shaver handpiece is not intended for use in neurosurgical procedures.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) SUMMARY

Submitter:	Bien-Air Surgery SA Rue De l'Ouest 2b 2340 Le Noirmont, Switzerland	
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Date Prepared:	September 26, 2017	
Proposed Device:	Manufacturer:	Bien-Air Surgery SA
	Common Name:	Cranial Drill Motor and accessories
	Trade/Device Name:	OSSEODUO Shaver and Drill System
	Classification Name:	Motor, Drill, Electric
	Regulation Number:	21 CFR 882.4360
	Regulation Name:	Electric cranial drill motor
	Regulatory Class:	Class II
	Product Code:	HBC, HBE
Primary Predicate Device:	Clearance:	K083720 March 20, 2009
	Manufacturer:	Bien-Air Surgery SA
	Trade 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
Predicate Device(s):	Clearance:	K080802 April 30, 2008
	Manufacturer:	The Anspach Effort, Inc.
	Trade Name:	eMax 2 Plus System
	Regulation Number:	21 CFR 882.4360
	Regulation Name:	Electric cranial drill motor
	Regulatory Class:	II
	Product Code:	HBC
Predicate Device:	Clearance:	K113476 December 16, 2011
	Manufacturer:	The Anspach Effort, Inc.
	Trade Name:	Dissection Tools
	Regulation Number:	21 CFR 882.4310
	Regulation Name:	Powered simple cranial drills, burrs, trephines, and their accessories
	Regulatory Class:	Class II
	Product Code:	HBE

Device Description: The OSSEODUO Shaver and Drill System is already cleared for other indications. This submission adds the PM2 Family of handpieces and accessories to the system with indications for shaping bones in spine and cranium surgical operations. These additional motors, NANO, RAPIDO, and PM PERFO incorporate previously cleared technology with a proprietary coupling. The available handpieces include 4 straight and five angled models, plus three fixed and two rotary craniotomies. Various burs are available that are sold sterile and for single use. The motors and handpieces are to be sterilized prior to first use and after each subsequent use. Validated processes for both cleaning and sterilization are included in the instructions.

Indications for Use Statement: The OSSEODUO system is intended for shaping bones in spine and cranium surgical operation. Shaver handpiece is not intended for use in neurosurgical procedures.

Summary of Technological Characteristics: Both the Bien-Air OSSEODUO Shaver and Drills system and Anspach eMax 2 Plus System feature electrical powered control units that connect with drill motors/handpieces combinations that drive burs in rotation in order to drill bone during surgical interventions. The operating principle and functionality are the same as follows.

	New Device: K173066 OSSEODUO (expanded Indications)	**OSSEODUO Shaver and Drills System K083720**	**eMax 2 Plus System and Dissection Tools K080802 and K113476**	
Indications for Use	The OSSEODUO system is intended for shaping bones in spine and cranium surgical operation. Shaver handpiece is not intended for use in neurosurgical procedures.	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 procedures (such as adenoidectomy, polypectomy, tonsillectomy)	The eMax 2 Plus System is intended for Cutting and shaping bone including spine and cranium.	Similar
Intended Use	Cutting soft tissue and bone	Cutting soft tissue and bone	Cutting bone	Similar
Controller	Console with foot pedal	Console with foot pedal	Console with foot pedal	Similar
Energy Source	Electrical	Electrical	Electrical	Similar
Speed Indication	Digital	Digital	Digital	Similar
Functions	Drill and Microdebrider	Drill and Microdebrider	Drill and Microdebrider	Similar
Drill Motor Speed	Max 80,000 rpm	Max 80,000 rpm	Max 80,000 rpm	Similar

Irrigation	1 peristaltic pump integrated into console for irrigation	1 peristaltic pump integrated into console for irrigation	1 pump integrated console for irrigation	Similar
Sterilization (Micromotors) (Handpieces)	Steam Autoclave AAMI TIR 12, ISO 17664, ISO 17665	Steam Autoclave AAMI TIR 12, ISO 17664, ISO 17665	Steam Autoclave AAMI TIR 12, ISO 17664, ISO 17665	Similar
Direct Contact Material	Stainless Steel / Diamond Grit	Stainless Steel	Stainless Steel/ Carbide	Differences

As with the predicate devices referenced above, the proposed device shares technological characteristics with the predicate devices. The indications for Use statement for the proposed device and the predicate devices are substantially equivalent, and the indications for the proposed device do not introduce any changes to the intended use. The proposed device and predicate devices contain a console and foot pedal and the consoles have 1 peristaltic pump integrated within for irrigation. The functions of the proposed device and predicate devices is a drill and microdebrider and the drill motor speed has a max rotation of 80,000 rpm. The speed indication on the proposed device and predicate device is digital. The proposed device as well as the predicate devices require steam autoclave sterilization for the drills and handpieces and follow AAMI TIR 12, ISO 17664, and ISO 17665. The direct contact material for the proposed device and predicate devices is stainless steel.

The proposed device also has some differences in technological characteristics from those of the predicate devices and any differences in the technological characteristics are minor and reflect market strategy and/or perceived user preferences and do not impact the safety, effectiveness, or substantial equivalence of the device. A direct contact material of the proposed device is diamond grit whereas the predicate devices do not contain diamond grit. The difference has been addressed by biocompatibility testing.

Summary of Non-Clinical / Test Data:

Test were performed on the OSSEODUO Shaver and Drill System which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate devices. Tests included verification/validation testing to internal functional specifications (including software). In addition, testing confirmed that the proposed device is equivalent to the predicate device for safety issues such as operating temperatures.
Documentation was provided demonstrating compliance of the device to all FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation plus traceability of verification/validation tests to software requirements and software risk hazards.

Testing confirmed that the device complies with relevant voluntary safety standards for Electrical Safety and Electromagnetic Compatibility testing, specifically IEC standards 60601-1 and 60601-1-2.

Together, these verification/validation activities successfully demonstrated that the device correctly performs as designed, has been validated for its intended use, and raises no new questions regarding either safety or effectiveness when compared to the predicate device. Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the device.

In addition, evaluations and validations have been performed to demonstrate compliance to the applicable standards for biocompatibility shown in the table below. The material-mediated pyrogenicity potential has been adequately evaluated for all materials, manufacturing processes and aids used in the manufacture of the patient-contacting device components. See

the summary table below. In addition, endotoxin testing was conducted with all testing meeting the acceptance criterion (< 2.15 EU/device).

Evaluation Test	Method/Model	Result
Cytotoxicity [ISO 10993-5]	MEM Elution	No cytotoxic potential
Irritation/ Intracutaneous Reactivity [ISO 10993-10] [ISO 10993-12]	Intracutaneous Reactivity in Rabbits (Two extracts: 0.9% NaCl; sesame oil)	Not reactive
Hemolysis [ISO 10993-4]	Material/surface-mediated hemolysis	No hemolytic effect
Sensitization [ISO 10993-10]	Sensitization in Guinea Pigs	No sensitization
Acute System Toxicity [ISO 10993-11]	Acute System Toxicity in Mice	No evidence of AST observed
Endotoxin [ISO 10993-5]	Gel-clot-method & Quantitative LAL test	Met acceptance criterion

For the accessories sold sterile for single use, the relevant successful sterilization validations and shelf life studies have been provided to support the labeled expiration dates.

Conclusion: Bien-Air Surgery SA considers the OSSEODUO Shaver and Drill System to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.