October 31, 2022

Bien-Air Surgery SA
℅ Akiko Dohi
Regulatory Scientist
Ken Block Consulting, LLC
800 East Campbell Road, Suite 202
Richardson, Texas 75081

Re: K213697
Trade/Device Name: ORiGO System
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric Cranial Drill Motor
Regulatory Class: Class II
Product Code: HBC, HBE
Dated: September 30, 2022
Received: September 30, 2022

Dear Akiko Dohi:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213697

Device Name
ORiGO System

Indications for Use *(Describe)*
The ORiGO System is a software-controlled motorized surgical system that includes attachments and tools for cutting bone, and provides irrigation fluid to the surgical site.
The ORiGO System is used in the following surgical fields:
-For cutting bones in neuro (cranial) and spinal surgeries.

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.

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510(k) SUMMARY

Submitter:	Bien-Air Surgery SA Rue de l'Ouest 2b Le Noirmont, Jura, 2340 Switzerland	
Contact Person:	Jonas Guerdat Chief Executive Officer TEL: +41-32-344-64-40 jonas.guerdat@bienair.com	
Date Prepared:	September 30, 2022	
Submission Type:	Traditional 510(k)	
Subject Device:	Manufacturer:	Bien-Air Surgery SA
	Trade Name:	ORiGO System
	Common Name:	Electrical Surgery System and Accessories
	Regulation Number:	21 CFR 882.4360
	Regulation Name:	Electric cranial drill motor
	Regulatory Class:	Class II
	Classification Product Code:	HBC
	Subsequent Product Code:	HBE
	Classification Name:	Motor, Drill, Electric
Predicate Device:	Clearance:	K173066 dated June 22, 2018
	Manufacturer:	Bien-Air Surgery SA
	Trade Name:	OSSEODUO Shaver and Drill System
	Common Name:	Cranial Drill Motor and Accessories
	Regulation Number:	21 CFR 882.4360
	Regulation Name:	Electric cranial drill motor
	Regulatory Class:	Class II
	Classification Product Code:	HBC
	Subsequent Product Code:	HBE
	Classification Name:	Motor, Drill, Electric

Device Description:

The ORiGO System is a software-controlled electrical surgery system intended to be used in an operating room by a clinician in a healthcare facility/hospital setting for cranial and spinal surgical procedures.

The ORiGO System consists of the ORiGO Control Unit, the ORiGO Foot Pedal, the ORiGO System-compatible two micromotors and one motorized handpiece with corresponding motor cables, handpieces, attachments, cutting tools, the ORiGO System Irrigation Line, and other accessories.

The ORiGO System transforms electrical energy through motors and converts it to rotational force to shape and cut bones through attached cutting tools.

Three micromotor subsystems of the ORiGO System include NANO, RAPIDO, and PM PERFO. The NANO and RAPIDO are micromotors. The PM PERFO is a motorized cranial perforator handpiece.

PM2 Handpieces are intended to be connected to the NANO Micromotor and RAPIDO Micromotor. Cranio-Guards are attached to the PM2 Handpieces, and craniotomy is performed using PM2 Craniotomy Burs. Other PM2 80K Burs are attached to the PM2 Handpieces without attachment. The PM2 80K Burs are used for cutting bones in cranial and spinal surgical procedures.

PM PERFO is intended to be used for a cranial perforation.

The ORiGO System is equipped with a peristaltic pump, which delivers saline irrigation solution to surgical sites through a 5m ORiGO System Irrigation Line.

The ORiGO System is a prescription-only device.

Indications for Use:

The ORiGO System is a software-controlled motorized surgical system that includes attachments and
tools for cutting bone, and provides irrigation fluid to the surgical site.
The ORiGO System is used in the following surgical fields:
* For cutting bones in neuro (cranial) and spinal surgeries.

Summary of Technological Characteristics:

Comparison with the predicate device shows the characteristics of the subject device, the ORiGO System, to be substantially equivalent to the predicate devices. As such, the ORiGO System and predicate devices have the same technological characteristics:

- Method of operation
- Motor subsystems and devices included in the systems

Following technological differences exist between the subject and the predicate devices:

- Additional cutting tools
- Longer motor cables and irrigation line
- Reprocessing instructions

These differences in the technological characteristics are minor and do not raise different questions of safety and effectiveness.

The following table summarizes the comparison of the subject ORiGO System to the predicate device in indications for use, design, operational principle, and technological characteristics.

	Subject Device	Predicate Device
Trade Name	ORiGO System	OSSEODUO Shaver and Drill System
510(k) Submitter [510(k) Number]	Bien Air Surgery SA [K213697]	Bien Air Surgery SA [K173066]
Product Code - Primary	HBC	HBC
Product Code - Subsequent	HBE	HBE
Indications for Use	The ORiGO System is a software-controlled motorized surgical system that includes attachments and tools for cutting bone, and provides irrigation fluid to the surgical site. The ORiGO System is used in the following surgical fields: * For cutting bones in neuro (cranial) and spinal surgeries.	The OSSEODUO system is intended for shaping bones in spine and cranium surgical operation. Shaver handpiece is not intended for use in neurosurgical procedures.
Intended Use	Cutting bone	Cutting bone

	Subject Device	Predicate Device
Controller	Console with Foot Pedal	Console with Foot Pedal
Energy Source	Electrical	Electrical
Speed Indication	Digital	Digital
Function	Drill	Drill and microdebrider
Drill Motor Speed	Max 80,000 rpm	Max 80,000 rpm
Irrigation	1 peristaltic pump integrated into the console for irrigation	1 peristaltic pump integrated into the console for irrigation
Sterilization	Steam Autoclave AAMI TIR 12, ISO 17664, ISO 17665	Steam Autoclave AAMI TIR 12, ISO 17664, ISO 17665
Direct Contact Material	Stainless Steel, Diamond Grit, Carbide, Full Carbide	Stainless Steel, Diamond Grit

Summary of Performance Testing:

The ORiGO System was developed and produced under considerations of all applicable technical standards, internal specifications, and FDA guidance documents. The conformance of the ORiGO System with applicable international and internal standards was verified during non-clinical bench testing and evaluation. Tests were performed on the subject device, which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate device.

Electromagnetic compatibility and electrical safety of the ORiGO System have been demonstrated in conformity with the FDA recognized consensus standard IEC 60601-1, 60601-1-2, and 60601-1-6 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”.

Software life cycle of the ORiGO System have been demonstrated in conformity with the FDA recognized consensus standard IEC 62304 “Medical device software - Software life cycle processes”.

Usability engineering to the ORiGO System has been demonstrated in conformity with the FDA recognized consensus standard IEC 62366-1 “Medical devices — Part 1: Application of usability engineering to medical devices”.

Documentation was provided demonstrating compliance of the ORiGO System devices to all FDA expectations stated in the FDA guidance documents “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,” “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, Pyrogen and Endotoxins Testing: Questions and Answers,” “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process”,” “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” Information to Support a Claim of Electromagnetic Compatibility (EMC) of “Electrically-Powered Medical Devices, Management of Cybersecurity in Medical Devices,” and “Postmarket Management of Cybersecurity in Medical Devices.”

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 devices. Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the ORiGO System.

Biocompatibility Testing:	Biocompatibility evaluations of the ORiGO System devices were selected in accordance with ISO 10993-1 Fifth edition 2018-08 "Biological evaluation of medical devices - Part 1: evaluation and testing within a risk management process" and the FDA guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"." The testing was conducted on the subject devices as determined by the risk analysis for the device and included: • Cytotoxicity per ISO10993-5 • Sensitization per ISO10993-10 • Irritation per ISO10993-10 • Acute Systemic Toxicity per ISO 10993-11 • Pyrogenicity per ISO 10993-11 • Indirect (extract) Hemolysis per ISO 10993-4 and ASTM F756
Discussion of the Clinical Tests:	Clinical testing was not required for a determination of substantial equivalence of the ORiGO System.
Conclusion:	Bien-Air Surgery SA considers the ORiGO 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.

Bien-Air Surgery SA

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