November 2, 2022

Bien-Air Surgery SA
% Yulia Nikova
Regulatory Affairs Manager
Ken Block Consulting LLC
800 E. Campbell Road, Suite 202
Richardson, Texas 75081

Re: K221184
Trade/Device Name: ORiGO 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, EQJ, NLY
Dated: October 4, 2022
Received: October 4, 2022

Dear Yulia Nikova:

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,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K221184

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 soft tissue and bone and provides irrigation fluid to the surgical site.

The ORIGO system is used in the following surgical fields:
• for cutting and shaping bones and resection of soft and hard tissues in the fields of head & neck/ENT (otology, rhinology, laryngology) and maxillofacial 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

K221184

Submitter:	Bien-Air Surgery SA Rue de l'Ouest 2b Le Noirmont, Jura, 2340 Switzerland	
Contact Person:	Mr. Jonas Guerdat Chief Executive Officer TEL: +41 (0)32 953 35 35 jonas.guerdat@bienair.com	
Date Prepared:	November 2, 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 874.4250
	Regulation Name:	Ear, nose, and throat electric or pneumatic surgical drill
	Regulatory Class:	Class II
	Classification Product Code(s):	ERL
	Subsequent Product Code(s):	EQJ, NLY
	Classification Name:	Drill, Surgical, Ent (Electric Or Pneumatic) Including Handpiece
Primary Predicate Device:	Clearance:	K083720 dated May 20, 2009
	Manufacturer:	Bien-Air Surgery SA
	Trade Name:	OSSEODUO Shaver and Drill System
	Common Name:	Electrical microresector, microdebrider, shaver blades, cannulae Electrical surgical drill, ENT drill, straight and angled handpieces, micro-saw handpieces Burs, saw blades
	Regulation Number:	21 CFR 874.4250
	Regulation Name:	Ear, nose, and throat electric or pneumatic surgical drill
	Regulatory Class:	Class II
	Classification Product Code(s):	ERL
	Classification Name:	Drill, Surgical, Ent (Electric Or Pneumatic) Including Handpiece
Predicate Device:	Clearance:	K143492 dated March 4, 2015
	Manufacturer:	Bien-Air Surgery SA
	Trade Name:	OSSEOSTAP Microdrill System
	Common Name:	Electrical surgical drill, ENT drill burs
	Regulation Number:	21 CFR 874.4250
	Regulation Name:	Ear, Nose, and Throat Electric Or Pneumatic Surgical Drill
	Regulatory Class:	Class II
	Classification Product Code(s):	ERL, EQJ

	Classification Name:	Drill, Surgical, Ent (Electric Or Pneumatic) Including Handpiece
Reference 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(s):	HBC
	Subsequent Product Code(s):	HBE
	Classification Name:	Motor, Drill, Electric

Device Description:

The ORiGO System is a software-controlled electrically-powered surgical system designed to be used in an operating room by a clinician for head & neck, ENT, and maxillofacial surgical procedures in a healthcare facility/hospital setting.

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

The ORiGO System transforms electrical energy through micromotors or motorized handpieces and converts it to rotational force to cut bones and resect soft and hard tissues through attached cutting tools.

Four motor subsystems of the ORiGO System include NANO, RAPIDO, OSSEOSTAP, and S120. The NANO and RAPIDO are micromotors. OSSEOSTAP is a motorized microdrill handpiece. S120 is a motorized shaver handpiece that is a microdebrider/microresector.

PM2 Handpieces are intended to be connected to the NANO Micromotor and RAPIDO Micromotor and used in conjunction with PM2 Burs. The PM2 80K Burs and PM2 50K Burs are used for cutting and shaping bones in ENT surgical procedures.

OSSEPSTAP is intended to be used for cutting and shaping bones in ENT surgical procedures, such as stapedotomy or ossiculoplasty. The OSSEOSTAP is used with OSSEOSTAP Burs and OSSEOSTAP Perforator.

S120 is intended to be used for resecting soft and hard tissues in ENT surgical procedures. The S120 is used with S120 Shaver Blades and S120 Shaver Burs.

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 soft tissue and bone, and provides irrigation fluid to the surgical site. The ORIGO system is used in the following surgical fields: • for cutting and shaping bones and resection of soft and hard tissues in the fields of head & neck/ENT (otology, rhinology, laryngology) and maxillofacial surgeries.
Summary of Technological Characteristics:	The ORiGO System has been designed to combine technical characteristics (or functions) of the previously cleared devices. As such, the OSSEOSTAP has been cleared through [K143492], while the S120 Shaver has been cleared through K083720. Additionally, the S120 reusable shaver blades have initially been cleared under [K083720] as Class I devices under the product code EQJ. The NANO Micromotor and RAPIDO Micromotor, used with the ORiGO System are identical to those of the OSSEODUO System [K173066], which is why it was selected as the reference device. All handpieces (PM2 Line Handpieces) used in conjunction with the two micromotors (NANO and RAPIDO) and cutting tools for the handpieces (PM2 Burs) from the OSSEODUO System [K173066] are also compatible and intended to be used with the ORiGO System. Comparison with the predicate devices 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 primary predicate and other predicate devices in indications for use, design, operational principle, and technological characteristics.

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	Substantial Equivalence Rationale
Trade Name	ORiGO System	OSSEODUO Shaver and Drill System	OSSEOSTAP Microdrill System	OSSEODUO Shaver and Drill System	N/A
510(k) Submitter [510(k) Number]	Bien Air Surgery SA [K221184]	Bien Air Surgery SA [K083720]	Bien Air Surgery SA [K143492]	Bien Air Surgery SA [K173066]	N/A
Product Code - Primary	ERL	ERL	ERL	HBC	Same as the primary predicate device
Product Code(s) - Subsequent	EQJ, NLY	N/A	EQJ	HBE	Same as the predicate device
Indications for Use	The ORiGO system is a software-controlled surgical system that is an active device transforming power supply energy into electrical energy to electronically control micromotors or motorized handpieces, including their attachments and tools, for cutting soft tissue and bone, and bringing irrigation fluid to the surgical site. The ORiGO system is used in the following surgical fields: • For cutting and shaping bones and resection of soft and hard tissues in the fields of head & neck/ENT (otology,	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)	The OSSEOSTAP system has been designed for the light drilling of bones as part of surgical operations such as stapedotomy or ossiculoplasty.	The OSSEODUO system is intended for shaping bones in spine and cranium surgical operation. Shaver handpiece is not intended for use in neurosurgical procedures.	Substantially equivalent

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	Substantial Equivalence Rationale
	rhinology, laryngology) and maxillofacial surgeries.	- Endoscopic dacryocystorhinostomy (DCR) - Nasopharyngeal and laryngeal procedures (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).			

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	Substantial Equivalence Rationale
Controller	Console with Foot Pedal	Console with Foot Pedal	Foot Controller	Console with Foot Pedal	Same as the primary predicate device and the reference device
Micromotors, Motorized Handpieces, and Handpieces	NANO Micromotor RAPIDO Micromotor OSSEOSTAP S120 Shaver PM2 Line	80K Micromotor S80 Shaver S120 Shaver	OSSEOSTAP	NANO Micromotor RAPIDO Micromotor 80K Micromotor PM2 Line	S120 Shaver: same as the primary predicate device OSSEOSTAP: same as the predicate device NANO Micromotor, RAPIDO Micromotor, amd PM2 Handpieces: same as the reference device
Cutting Instruments	PM2 Burs OSSEOSTAP Burs S120 Shaver Blades S120 Shaver Burs	S120 Shaver Blades S120 Shaver Burs	OSSEOSTAP Burs	PM2 Burs	S120 Shaver Blades and S120 Shaver Burs: same as the primary predicate device OSSEOSTAP Burs: same as the predicate device PM2 Burs: same as the reference device
Energy Source	Electrical	Electrical	Electrical	Electrical	Same
Speed Indication	Digital	Digital	N/A	Digital	Same as the primary predicate device and the reference device
Function	Drill and microdebrider	Drill and microdebrider	Drill	Drill and microdebrider	Same as the primary predicate device and the reference device
Drill Motor Speed	Max 80,000 rpm	Max 80,000 rpm	Max 12,000 rpm	Max 80,000 rpm	Same as the primary predicate device and the reference device

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	Substantial Equivalence Rationale
Irrigation	1 peristaltic pump integrated into the console for irrigation	1 peristaltic pump integrated into the console for irrigation	N/A	1 peristaltic pump integrated into the console for irrigation	Same as the primary predicate device and the reference device
Sterilization	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	Steam Autoclave AAMI TIR 12, ISO 17664, ISO 17665	Same
Direct Contact Material	Stainless Steel/ Diamond Grit, Carbide	Stainless Steel	Stainless Steel/ Diamond Grit	Stainless Steel/ Diamond Grit	Substantially equivalent

Summary of Performance Testing:	As required by 21 CFR 820.30(g), the ORiGO System has been successfully subjected to design validation, including software validation. Non-clinical bench testing of the ORiGO System device has been carried out to cover functional verification, device performance, and usability. 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 following 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 • Material-Mediated Pyrogenicity per ISO 10993-11
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 the intended use, principles of operation, functional design, and established medical use.