September 20, 2024

Saeshin Precision Co., Ltd.
% Sanghwa Myung
Regulatory Affairs Consultant
E & M
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South Korea

Re: K233153
Trade/Device Name: Traus SSG10 Surgical System
Regulation Number: 21 CFR 882.4360
Regulation Name: Electric Cranial Drill Motor
Regulatory Class: Class II
Product Code: HBC
Dated: August 16, 2024
Received: August 16, 2024

Dear Sanghwa Myung:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S
Digitally signed by Adam D. Pierce -S
Date: 2024.09.20 16:39:32 -04'00'

Adam D. Pierce, Ph.D.
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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)*
K233153

Device Name
Traus SSG10 Surgical System

Indications for Use *(Describe)*
Traus SSG10 Surgical System is an electrical appliance intended to cut, shave, bone & tissue resection, grinding, and drilling in the cranium and spine. 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.

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

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K233153

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Date 510(k) summary: September 16th, 2024

Trade/common Name: Traus SSG10 Surgical System
Regulation Name: Electric cranial drill motor
Regulation Numbers: 872.4360
Product Code: HBC, HBE
Classification: Class II

Description of Device:

Traus SSG10 Surgical System is composed of a control box, micro motor and a foot controller as an electric bone surgery machine. A signal for operating a foot controller, a handpiece, etc.., is transmitted when a power source is inputted to a control box (main body) to control functions such as rotational speed, torque and water injection amount.

It is a mechanism for puncturing, and cutting bones and human tissues through rotation and reciprocating motion by connecting handpieces and attachments to a micro motor. Three modes (Drill, Saw, Shaver) can be set, and the handpiece and attachment for each mode can be used in many surgical areas.

Indications for Use

Traus SSG10 Surgical System is an electrical appliance intended to cut, shave, bone & tissue resection, grinding, and drilling in the cranium and spine. Shaver handpiece is not intended for use in neurosurgical procedures

Predicate Device:

Manufacturer: Bien-Air Surgery SA
510(k) Number: 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

Comparison table is as follows.

Table 1: Substantial equivalence comparison: Predicate Device

Descriptive Information	Subject Device	Predicate Device	Comparison Comment
Manufacturer	Saeshin Precision Co., Ltd.	Bien-Air Surgery SA	-
Device Name	TRAUS SSG10 Surgical System	OSSEODUO Shaver and Drill System	-
510(k) number	K233153	K173066	-
Classification Product Code / Regulatory Number	HBC 21 CFR 882.4360	HBC 21 CFR 882.4360	-
Regulatory Class	Class II	Class II	-
Indications for Use	Traus SSG10 Surgical System is an electrical appliance in the form of an electric console-type product that connects with a handpiece to cut, shave, bone & tissue resection, grinding, and drilling.	The OSSEODUO system is intended for shaping bones in spine and cranium surgical operation. Shaver handpiece is not intended for use in neurosurgical procedures.	Substantial Equivalent
Controller	Console with Foot pedal	Console with Foot pedal	Substantial Equivalent
Speed Indication	Digital	Digital	Substantial Equivalent
Function	Drill, Saw, Shaver	Drill and Microdebrider(Shaver)	Substantial Equivalent

Energy Source	Electrical	Electrical	Substantial Equivalent
Motor Speed	Max. 40,000rpm	Max 80,000rpm	#1 Different
Sterilization	Steam Autoclave ISO 17665-1:2006	Steam Autoclave AAMI TIR12, ISO 17664, ISO17665	Substantial Equivalent
Irrigation	1 peristaltic pump integrated into console for irrigation	1 peristaltic pump integrated into console for irrigation	Substantial Equivalent

Discussion

The predicate device OSSEODUO Shaver and Drill System, has 80,000 Max rpm. In this respect, the performance is different from that of subject device, Traus SSG10 Surgical System, which is Max. 40,000 rpm.

The subject device safety was conducted according to IEC 60601-1 with the above differences. Performance test (Bench test) also was conducted. The testing results show that the difference does not raise any problems in the safety and effectiveness.

Biocompatibility: Materials tested in accordance with 10993-1 are used and materials that have been confirmed to be biologically safe are used.

1) ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

2) ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

3) ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

4) ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials

Non-clinical Performance Data:

(1) Electrical Safety and electromagnetic compatibility (EMC)

Electrical safety, EMC and device-related electrical safety for high frequency were conducted on the Traus SSG10 according to the following consensus standards:

• IEC60601-1:2005/AMD2:2020, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance

• IEC 60601-1:2015+A1:2021, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic

(2) Software Verification and Validation Testing

Software verification and validation testing was conducted for the subject device, and documentation was provided in accordance with FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices", May 11, 2005, commensurate with a moderate level of concern. IEC 62304 including results of verification/validation plus traceability of verification/validation tests to software requirements and software risk hazards.

(3) Performance Testing

We conducted bench testing to assure that the SSG 10 operates safely and within the predefined design specifications. We declare our performance report based on performance criteria such as RPM.

(4) Sterilization

Sterilization has been validated in conformance to the FDA recognized consensus standard ISO 17665-1:2006 Sterilization of health care products – moist heat – Part 1: requirements for the development, validation and routine control of a sterilization process for medical devices.

Clinical Data: No clinical performance testing was performed.

Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the SSG10 device should perform as intended in the specified use conditions. The non-clinical data demonstrate that the SSG10 device performs comparably to the predicate device that is currently marketed for the same intended use Based on the available information, the subject device and the predicates are similar indication for use, operational principal, performance data. In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification that we conclude that substantially equivalent with predicate device.