July 13, 2020

Saeshin Precision Co., Ltd.
Jong Choi
Quality Manager
52, Secheon-ro 1-gil, Dasa-eup, Dalseong-gun
Daegu, 42921 Kr

Re: K192561
Trade/Device Name: TRAUS SUS20
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: DZI
Dated: June 18, 2020
Received: June 25, 2020

Dear Jong Choi:

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K192561

Device Name
TRAUS SUS20

Indications for Use *(Describe)*
TRAUS SUS20, Piezo Surgery Engine Set, is intended for use in dental surgery including:
osteotomy, osteoplasty, periodontal surgery and implantation.

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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K192561
510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 10, 2020

1. Applicant / Submission Sponsor

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2. Submission Correspondent

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3. Device Identification

- Trade/Proprietary Name: TRAUS SUS20
- Classification Name: Bone cutting instrument and accessories.
- Classification Regulation: 21CFR872.4120
- Product Code: DZI
- Device Class: 2
- Review Panel: Dental

4. Predicate Device

- K number: K151171
- Manufacturer: Saeshin Precision Co., Ltd.
- Trade Name: TRAUS SUS10

(Reference Device: Compact Piezo LED, K151023)

5. Device Description

TRAUS SUS20 has the function of piezo surgery by using ultrasonic mechanical vibration. TRAUS SUS20 consists of a control box (main unit), a piezo handpiece and a foot controller.

When the AC power is connected to the control box by the power cord, the control box has a program for ultrasonic surgery mode which be able to set such as power (output intensity) and boost (vibration frequency).

6. Intended use / Indications for Use

TRAUS SUS20, Piezo Surgery Engine Set, is intended for use in dental surgery including: osteotomy, osteoplasty, periodontal surgery and implantation.

7. Substantial Equivalence

The subject device, TRAUS SUS20 is derived from the predicate device, TRAUS SUS10. The predicate device, TRAUS SUS10 has two functions as a piezo ultrasonic dental surgery function and a motor based dental surgery function. The subject device, TRAUS SUS20 has only piezo ultrasonic surgery function and it is the same as the predicate device.

TRAUS SUS20 is substantially equivalent to the predicate device, TRAUS SUS10 (K151171), in which the principle of operation, intended use, technological characteristics and performance characteristics are same. The differences have been verified and the result shows that it does not raise any new questions of safety and effectiveness. The reference device K151023 is used for substantial equivalence comparison of the LED functionality only.

The following comparison table is presented to demonstrate substantial equivalence.

-	Subject Device	Predicate Device	Reference Device	Comparison
Manufacturer	Saeshin Precision Co., Ltd.	Saeshin Precision Co., Ltd.	Mectron Spa	-
Device Name	TRAUS SUS20	TRAUS SUS10	Compact Piezo LED	-
510(k) number	-	K151171	K151023	-
Classification Product Code / Regulatory Number	DZI / 872.4120	DZI / 872.4120	ELC / 872.4850	Identical to Predicate Device
Subsequent Product Code	None	EGS, EBW	Non	-
Regulatory Class	2	2	2	Identical to Predicate Device
Indications for Use	TRAUS SUS20, Piezo Surgery Engine Set, is intended for use in dental surgery including: osteotomy, osteoplasty, periodontal surgery and implantation.	TRAUS SUS10, Piezo Surgery and Implant Engine Unit, is intended for use in dental surgery including: osteotomy, osteoplasty, periodontal surgery and implantation (for ultrasonic surgery), and implantology, maxilla-facial surgery and endodontics for treatment of dental hard tissue and mechanical rotating root canal preparation (for dental	The Compact Piezo LED is an ultrasonic scaler intended for use, with the appropriate associated insert tips, in the following dental applications: • Scaling: Procedures for removal of supragingival/ subgingival and interdental calculus/plaque deposits; • Periodontology:	Very similar to Predicate Device

		implant surgery).	Periodontal therapy and debridement for periodontal diseases, including periodontal pocket irrigation and cleaning; • Endodontics: Treatments for root canal reaming irrigation, revision, filling, gutta-percha condensation and retrograde preparation; • Restorative and Prosthetics: Restorative procedures including cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations, inlay/onlay condensation and implants/restorations cleaning.	
Prescription or OTC	Prescription	Prescription	Prescription	Identical to Predicate Device
Principle of Operation	Piezoelectric ultrasonic vibrations to perform in dental surgery	Piezoelectric ultrasonic vibrations to perform in dental surgery	Piezoelectric ultrasonic vibrations to perform in dental surgery	Identical to Predicate Device
Device Design - Control box				
Model Name	TRAUS BUS20	TRAUS XUS10	None	Identical to Predicate Device
Input Power	AC 100-120V, 50 / 60 Hz, 48VA	AC 100-120V, 50 / 60 Hz, 48VA	None	Identical to Predicate Device
Max. Irrigation Volume	Max. 110Q/min ± 20%	Max. 90Q/min ± 20%	None	Identical to Predicate Device
Device Design - Piezo Handpiece				
Model Name	TRAUS PEZ10XX (Non-optic), TRAUS PEZ10LN (Optic)	TRAUS PEZ10XX (Non-optic)	COMPACT PIEZO LED	-
Vibration frequency	27 ± 3KHz	27 ± 3KHz	24 kHz to ~36 kHz	Identical to Predicate Device

Maximum output power of piezo operation	59 VA	59VA	59VA	Identical to Predicate Device
LED system incorporated inside the handpiece to provide illumination of the operative site	Yes (only for TRAUS PEZ10LN / 2,400 lux)	None	Yes	Identical to Reference Device
Device Design - Ultrasonic Tip (Not provided)				
Model Name	FDA listed accessory (Listing number D250061) SP-028i SP-024i SP-016 SP-SAW SP-SAW L SP-SAW R SP-320 SP-400 SP-610 SP-020is	FDA listed accessory (Listing number D250061) SP-028i SP-024i SP-016 SP-SAW SP-SAW L SP-SAW R SP-320 SP-400 SP-610 SP-100 SP-020is	FDA listed accessory OT7 OT7S-3 OT7S-4 OT8R OT9L	Identical to Predicate Device
Material (in contact with patient)	Trimrite	Trimrite	Trimrite	Identical to Predicate Device
Device Design - Foot Controller				
Model Name	TRAUS FUS10	TRAUS FUS10	NA	Identical to Predicate Device
Degree of protection against ingress of water (IEC 60529)	IPX8	IPX8	NA	Identical to Predicate Device
Accessories				
Handpiece Stand	Part No. 2017 STANDER	Part No. 2011 STAND	NA	Identical to Predicate Device
Hanger	Part No. X-CUBE 06	Part No. X-CUBE 06	NA	Identical to Predicate Device
Tube Holder	Part No. FORTE 100*a*EI 05	Part No. FORTE 100*a*EI 05	NA	Identical to Predicate Device
Torque wrench	Part No. TRAUS ATW10	Part No. TRAUS ATW10	NA	Identical to Predicate Device

Tip Holder	Part No. TRAUS ATH10	Part No. TRAUS ATH10	NA	Identical to Predicate Device
Sterilization Case	Part No. TRAUS ATR10	Part No. TRAUS ATR10	NA	Identical to Predicate Device
Power Cord	Part No. BC-02	Part No. BC-02	NA	Identical to Predicate Device
(Optional) Irrigation Tube	* FDA listed accessory. (Listing No: D289551) Part No. DB-001, Part No. DB-003	* FDA listed accessory. (Listing No: D289551) Part No. DB-001, Part No. DB-003	NA	Identical to Predicate Device

8. Electrical Safety and Electromagnetic compatibility

The Electrical Safety and Electromagnetic Compatibility tests were performed in accordance with the following standards.

- IEC 60601-1:2005 + A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 80601-2-60:2012, Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
- IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

9. Software Validation:

TRAUS SUS20 contains MODERATE level of concern software (firmware). The software was designed and developed according to a software development process and was verified and validated.

Software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices.

10. Biocompatibility

TRAUS SUS20 is supplied with piezo handpiece which can contact with a patient. The handpiece has been evaluated about biocompatible throughout previous FDA clearance (K151171) as the materials and manufacturing process are identical to the company's own predicate device.

The ultrasonic tips which also can contact with a patient are FDA listed accessories (Listing number D250061). The biocompatibility test for the tips were performed in accordance with the following FDA recognized standards

- ISO 10993-1: 2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.
- ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.

10. Sterilization

The piezo handpiece, ultrasonic tip and torque are sterilized by the user prior to use. The sterilization was validated in accordance with the standard ISO 17665-1.

11. Nonclinical Performance Test – Bench Test

For nonclinical performance testing – Bench test, piezo output frequency, Piezo output power and Irrigation water flow rates were evaluated according to SOP.

12. Clinical Testing

No clinical study was considered necessary and performed.

13. Conclusion

Under the comparing substantial equivalence between the subject device and the predicate device, there are the same points such as Product Code, Regulation number, Classification, Indications for use, Principle of Operation and Design Specification (Maximum output power of piezo operation and Vibration frequency). A piezo handpiece (TRAUS PEZ10XX) and foot controller (TRAUS FUS10) are identical to the predicate device. Although there are some differences Control box - Max. irrigation volume, a handpiece with optic function, ultrasonic tips), the performance test reports are supported to the substantial equivalence of the subject device. The differences of the subject device do not raise different questions of safety and effectiveness. The subject device follows the recommendations of the FDA Guidance Document Dental Handpieces – Premarket Notification [510(k)] Submissions.

In this regard, we conclude that the subject device is substantially equivalent to the predicate device.