February 11, 2021

Saeshin Precision Co., Ltd.
% Dongha Lee
Regulatory Affairs Consultant
KMC, Inc.
Room no. 904, 27, Digital-ro 27ga-gil, Guro-gu
Seoul, 08375
REPUBLIC OF KOREA

Re: K201292
Trade/Device Name: TRAUS SIP20
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I, reserved
Product Code: EBW, EGS
Dated: January 15, 2021
Received: January 26, 2021

Dear DongHa Lee:

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,

Michael E. Adjodha, M.ChE.
Assistant 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)*
K201292

Device Name
TRAUS SIP20

Indications for Use *(Describe)*
TRAUS SIP20 is intended for use in dental surgery, implantology, for treatment of dental hard tissue and mechanical rotating root canal preparation.

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 (K201292)

This summary of 510(K) - substantial equivalence information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: February 10, 2021

1. Applicant / Submission Sponsor

Saeshin Precision Co., Ltd.
Address: #52, Secheon-ro 1-gil, Dasa-eup, Dalseong-gun, Daegu 42921 Republic of Korea
Tel : +82-53-587-2345 Fax : +82-53-580-0939

2. Submission Correspondent

DongHa Lee (Consultant, KMC, Inc.)
Address: Room no. 904, 27, Digital-ro 27ga-gil, Guro-gu, Seoul, 08375, Korea
Tel: +82-70-8965-5554 Fax: +82-2-856-5904
Email: dhlee@kmcerti.com

3. Device Identification

- Trade/Proprietary Name: TRAUS SIP20
- Classification Name: Dental handpiece and accessories
- Classification Regulation: 21CFR 872.4200
- Product Code: EBW, EGS
- Device Class: 1
- Review Panel: Dental

4. Primary Predicate Device

- K number: K123695
- Manufacturer: Saeshin Precision Co., Ltd.
- Trade Name: TRAUS SIP10

5. Reference Device

- K number: K182892
- Manufacturer: Saeshin Precision Co., Ltd.
- Trade Name: TRAUS Dental Handpieces

4. Device Description

TRAUS SIP20 is an AC-powered device that includes a hand-held motor, controller, contra angle handpiece and foot controller for regulation of speed and direction of rotation or a contra-angle attachment for dental surgery.

5. Indications for Use

TRAUS SIP20 is intended for use in dental surgery, implantology, for treatment of dental hard tissue and mechanical rotating root canal preparation.

6. Substantial Equivalence

The subject device, TRAUS SIP20 is derived from the primary predicate device, TRAUS SIP10.

Under the comparing substantial equivalence between the subject device and the primary predicate device, there are the same points such as Product Code, Regulation number, Classification, Indications for use, and Principle of Operation. Besides, Micro motors (TRAUS MBP10SX and TRAUS MBP10SL), Angle handpieces (TRAUS CRB26LX, TRAUS CRB26XX, TRAUS CRB27LX and TRAUS CRB27XX) and foot controller (TRAUS FUS10) are identical to the primary predicate device. The newly added angle handpieces (TRAUS CRB46LN, TRAUS CRB46NN) for the subject device are identical to the reference device which is FDA cleared components (K182892).

Although there are some differences between the subject device and the primary predicate device such as control box specification (gear ratio and maximum irrigation volume), new angle handpieces (TRAUS CRB46LN and TRAUS CRB46NN), the safety and performance test reports are supported to the substantial equivalence. The differences do not raise different questions of safety and effectiveness.

The following comparison table is presented to demonstrate substantial equivalence.

Descriptive Information	Subject Device	Primary Predicate Device	Reference Device	Comparison
Manufacturer	Saeshin Precision Co., Ltd.	Saeshin Precision Co., Ltd.	Saeshin Precision Co., Ltd.	The same
Device Name	TRAUS SIP20	TRAUS SIP10	TRAUS Dental Handpieces	-
510(k) number	-	K123695	K182892	-

Classification Product Code / Regulatory Number	EBW, EGS / 872.4200	EBW, EGS / 872.4200	EGS / 872.4200	The same
Regulatory Class	1	1	1	The same
Indications for Use	TRAUS SIP20 is intended for use in dental surgery, implantology, for treatment of dental hard tissue and mechanical rotating root canal preparation.	TRAUS SIP10 is intended for use in dental surgery, implantology, maxilla-facial surgery and endodontics for treatment of dental hard tissue and mechanical rotating root canal preparation.	The TRAUS Dental Handpieces are indicated for wide range of dental procedures. A. Implant placement, including 1. Preparation of the osteotomy site 2. Bone contouring, osteoplasty B. Periodontal surgeries 1. Bone contouring & alveoplasty around living teeth 2. Removal of exostosis C. Bone grafting 1. Preparation of the donor site (for e.g. symphysis and ascending rames etc.) 2. Harvesting autogen living bone 3. Sinus elevation & grafting of alveolar sockets D. Removal and sectioning of teeth and teeth bone for e.g.	The same as the primary predicate device.

			impacted third molars and complicated extractions	
Prescription or OTC	Prescription	Prescription	Prescription	The same
Principle of Operation	Dental handpiece is driven by electrical micromotor and internal gearings. The micromotor and internal gearings are controlled by a control box.	Dental handpiece is driven by electrical micromotor and internal gearings. The micromotor and internal gearings are controlled by a control box.	Dental Handpiece is gear driven hand-held dental handpieces. It can be driven by torque adjustable electrical motors for surgery treatment.	The same as the primary predicate device.
Components	Control box, Foot controller, Micro motor, Handpieces	Control box, Foot controller, Micro motor, Handpieces	Handpieces	The same as the primary predicate device.
Device Design - Control box				
Model Name	TRAUS BIP20	TRAUS XIP10	N/A	-
Input Power	AC 100-120V, 50 / 60 Hz, 48VA	AC 100-120V, 50 / 60 Hz, 120W		Different
Gear Ratio	1:1, 1:2, 1:5, 16:1, 20:1, 32:1	1:1, 16:1, 20:1, 27:1, 32:1, 64:1		Different
LED Optic / Light Intensity	25,000 lux	25,000 lux		The same
Max. Irrigation Volume	Max. 90㎖/min ± 20%	Max. 75㎖/min		Different
Device Design - Foot controller				
Model Name	TRAUS FUS10	TRAUS FUS10	N/A	Same component as the primary predicate device
Degree of protection against ingress of water (IEC 60529)	IPX8	IPX8		
Device Design - Micro motor				

Model Name	TRAUS MBP10SX, TRAUS MBP10SL	TRAUS MBP10SX, TRAUS MBP10SL	N/A	Same components as the primary predicate device
Fiber optics	N/A	N/A		
Motor Type	BLDC	BLDC		
RPM	40,000 rpm	40,000 rpm		
Fiber optics	Only for TRAUS MBP10SL	Only for TRAUS MBP10SL		
Device Design - Angle Handpiece				
Model Name	TRAUS CRB26LX, TRAUS CRB26XX, TRAUS CRB27LX, TRAUS CRB27XX, TRAUS CRB46LN, TRAUS CRB46NN	TRAUS CRB26LX, TRAUS CRB26XX, TRAUS CRB27LX, TRAUS CRB27XX,	TRAUS CRB46LN TRAUS CRB46NN	Same components as the primary predicate device or the reference device
Fiber optics	Only for TRAUS CRB26LX, TRAUS CRB27LX, TRAUS CRB46LN,	Only for TRAUS CRB26LX, TRAUS CRB27LX	Only for TRAUS CRB46LN,	
Rear Ratio	20:1 (TRAUS CRB26LX, TRAUS CRB26XX) 32:1 (TRAUS CRB27LX, TRAUS CRB27XX) 20:1 (TRAUS CRB46LN, TRAUS CRB46NN)	20:1 (TRAUS CRB26LX, TRAUS CRB26XX) 32:1 (TRAUS CRB27LX, TRAUS CRB27XX)	20:1 (TRAUS CRB46LN, TRAUS CRB46NN)	

Speed in rpm	Max. 2,000 rpm (TRAUS CRB26LX, TRAUS CRB26XX) Max. 1,250 rpm (TRAUS CRB27LX, TRAUS CRB27XX) Max. 2,000 rpm (TRAUS CRB46LN, TRAUS CRB46NN)	Max. 2,000 rpm (TRAUS CRB26LX, TRAUS CRB26XX) Max. 1,250 rpm (TRAUS CRB27LX, TRAUS CRB27XX)	Max. 2,000 rpm (TRAUS CRB46LN, TRAUS CRB46NN)	
Material (in contact with patient)	SUS 303F SUS 420F	SUS303F SUS 420F	SUS303F SUS 420F	
Chuck Design	For Shank Type 1 by ISO 1797	For Shank Type 1 by ISO 1797-1	For Shank Type 1 by ISO 1797-1	
Bur Extraction Force	45 N	45 N	45 N	
Conformance with standards for shanks	Shank Type: Type 1 by ISO 1797	Shank Type: Type 1 by ISO 1797-1	Shank Type: Type 1 by ISO 1797	
Coupling dimensions for micro motor	ISO 3964	ISO 3964	ISO 3964	

7. 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

8. Software Validation:

TRAUS SIP20 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.

9. Biocompatibility

The handpiece has been completely evaluated and cleared through the previous FDA 510K (K123695 and K182892) as the same materials and the same manufacturing process as the company's own devices. (There have been no design changes in any of these models.)

In comparing the biocompatibility of the device with the primary predicate device and reference device, it is demonstrated that the device has the same type of patient contacting parts, which are classified the same concerning body contact and contact duration.

Based on the above evaluation, the dental handpieces are substantially equivalent to the primary predicate devices in terms of biocompatibility.

10. Sterilization

The sterilization validation of the applied components (Micro motor, motor cap, Angle Handpiece) has been completely evaluated and cleared through the previous FDA 510K (K123695 and K182892) as the same materials and the same manufacturing process as the company's own devices. (There have been no design changes in any of these models (micromotors and handpieces))

11. Nonclinical Performance Test – Bench Test

The performance tests were conducted as bench test according to ISO 14457: 2017.

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, and Principle of Operation. Besides, Micro motors (TRAUS MBP10SX and TRAUS MBP10SL), Angle handpieces (TRAUS CRB26LX, TRAUS CRB26XX, TRAUS CRB27LX and TRAUS CRB27XX) and foot controller (TRAUS FUS10) are identical to the predicate device. The newly added angle handpieces (TRAUS CRB46LN, TRAUS CRB46NN) for the subject device are identical to the reference device which is FDA cleared components (K182892).

Although there are some differences between the subject device and the predicate device such as control box specification (gear ratio and maximum irrigation volume), new angle handpieces (TRAUS CRB46LN and TRAUS CRB46NN), the safety and performance test reports are supported to substantial equivalence. The differences do not raise different questions of safety and effectiveness.

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