June 24, 2022

Saeshin Precision Co., Ltd.
℅ Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, California 92612

Re: K212043
Trade/Device Name: TRAUS ENDO
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: May 16, 2022
Received: May 26, 2022

Dear Priscilla Chung:

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 Michael E. Adjodha, M.ChE.
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)*
K212043

Device Name
TRAUS ENDO

Indications for Use *(Describe)*
The TRAUS ENDO, ACL(B)-41EP, ACL(B)-42EP, and ACL(B)-46EP, are indicated for use by dentists in standard endodontic procedures using rotary files and rotary endodontic drills (Gates-Glidden).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(K212043)

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

1. Date: 6/23/2022

2. Applicant / Submitter

Saeshin Precision Co., Ltd.
52, Secheon-ro 1-gil, Dasa-eup Dalseong-gun, Daegu, 711-814, Korea
Tel: +82 53 587 2345 / Fax:+82 53 580 0918

3. U.S. Designated Agent

Priscilla Chung
LK Consulting Group USA, Inc.
18881 Von Karman Ave. STE 160
Irvine, CA 92612
Tel: 714.202.5789 Fax: 714.409.3357
Email: juhee.c@LKconsultingGroup.com

4. Trade/Proprietary Name:

TRAUS ENDO

5. Common Name:

Dental Handpiece

6. Classification:

Handpiece, Direct Drive, Ac-Powered (21CFR 872.4200, Product code EKX, Class I, Dental)

7. Device Description:

The TRAUS ENDO is an AC-powered device that includes a power unit, charging station and contra-angle handpieces, ACL(B)-41EP, ACL(B)-42EP, and ACL(B)-46EP, which are used for grinding, cutting, and polishing work in dental oral use. It is used for endodontic surgery with 600-1,000 rpm.

8. Indication for use:

The TRAUS ENDO, ACL(B)-41EP, ACL(B)-42EP, and ACL(B)-46EP, are indicated for use by dentists in standard endodontic procedures using rotary files and rotary endodontic drills (Gates-Glidden).

9. Primary Predicate Device:

- TRAUS ENDO (K143411) by Saeshin Precision Co., Ltd.

10. Additional Predicate/Reference Device:

- STRONG Dental Handpieces (K181129) by Saeshin Precision Co., Ltd.
- ENDO a class (K123582) by Saeyang Microtech Co., Ltd.

11. Substantial Equivalence:

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device
Manufacturer	Saeshin Precision Co., Ltd.	Saeshin Precision Co., Ltd.	Saeshin Precision Co., Ltd.	Saeyang Microtech Co., Ltd.
Device Name	TRAUS ENDO	TRAUS ENDO	STRONG Dental Handpieces	ENDO a class
510(k) Number	K212043	K143411	K181129	K123582
Device Classification Name	Handpiece, direct drive, AC-powered	Handpiece, direct drive, AC-powered	Handpiece, direct drive, AC-powered	Handpiece, direct drive, AC-powered
Classification Product Code	EKX	EKX	EGS	EKX
Device Class	I	I	I	I
Regulation Number	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200
Indication for Use	The TRAUS ENDO, ACL(B)-41EP, ACL(B)-42EP, ACL(B)-46EP, are indicated for use by dentists in standard endodontic procedures using rotary files and rotary endodontic drills (Gates-Glidden).	The TRAUS ENDO, ACL(B)-41EP, ACL(B)-42EP, and ACL(B)-45EP, are indicated for use by dentists in standard endodontic procedures using rotary files and rotary endodontic drills (Gates- Glidden).	The Strong Dental Handpiece, ACL(B)–46EP is intended for wide range of dental procedures, including: 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 Sinus elevation & grafting of alveolar sockets 3. D. Removal and sectioning of teeth and teeth bone for e.g. impacted third molars and complicated extractions.	This application area extends to endodontic procedures using a root canal instrument which is intended by the manufacturer for use in the mechanical and rotary preparation of root canals.
Components	Contra-Angle Handpiece Motor Handpiece Battery Charger Power Cord	Contra-Angle Handpiece Motor Handpiece Battery Charger Power Cord	Contra-Angle Handpiece	Contra-Angle Handpiece Motor Handpiece Battery Charger Power Cord
Gear	10:1 16:1 20:1	16:1 20:1 32:1	10:1	4:1 10:1 16:1 20:1

Chuck Type	Latch Type	Latch Type	Latch Type	Latch Type
Shank Type	Type 1	Type 1	Type 1	Type 1
Composition of Material	• Gear: Stainless steel • Shank: Stainless steel (Trimrite) & Brass • Head: Stainless steel Chuck: Aluminum	• Gear: Stainless steel • Shank: Stainless steel (Trimrite) & Brass • Head: Stainless steel Chuck: Aluminum	• Gear: Stainless steel • Shank: Stainless steel (Trimrite) & Brass • Head: Stainless steel Chuck: Aluminum	Stainless Steel
Supply voltage	100-240V AC 50/60Hz	100-240V AC 50/60Hz	-	100-240V AC 50/60Hz
Operational voltage	DC 4.5V	DV 4.5V	-	-
Torque moto speed	1-4 Ncm	1-4 Ncm	2 Ncm	1-4 Ncm
Sterilization	Contra-angle at 132°C for 4 minutes in Autoclave	Contra-angle at 132°C for 4 minutes in Autoclave	Contra-angle at 132°C for 4 minutes in Autoclave	-
Electrical safety	conforms IEC 60601-1 IEC 60601-1-2 ISO 14457	conforms IEC 60601-1 IEC 60601-1-2 ISO 14457	conforms ISO 14457	conforms IEC 60601-1 IEC 60601-1-2
Allows selection of forward or Auto reverse drive rotation	Yes	Yes	-	Yes
Allows reciprocation drive	Yes	No	-	Yes

The indications for use and the technological characteristics of the subject device is the same as the predicate device, the unmodified devices. The ACL(B)-41EP and the ACL(B)-42EP are cleared under K143411 and the ACL(B)-46EP is cleared under K181129. The modification is adding reciprocation mode and we identified a reference device (K123582) which offers the same mode.

We performed risk analysis and verification/validation tests per modifications, and the test results support that the modification raises no new safety and effectiveness questions.

12. Performance Data:

The following tests were conducted, and the device passed all of the tests based on pre-determined Pass/Fail criteria.

- Software Verification/Validation (EN 62304).
- Temperature Test (ISO 14457, IEC 80601-2-60)
- Eccentricity Test (ISO 14457)

We also referenced the FDA Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" while preparing the software documentation.

Biocompatibility Testing per ISO 10993 was assessed under K143411, the previous cleared device, which has the same patient contacting material and manufacturing processes as the subject device.

Reprocessing Validation (i.e., Cleaning, Sterilization per ISO 17665-1) was assessed under K143411 and K181129, the previously cleared devices.

13. Conclusion:

The subject device is substantially equivalent in the areas of technical characteristics, general function, application, and indications for use. The subject device does not introduce a fundamentally new scientific technology, and the device has been validated through system level test. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.