November 26, 2019

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

Re: K182892
Trade/Device Name: TRAUS Dental Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EGS
Dated: August 21, 2019
Received: September 3, 2019

Dear Choi Jong Woo:

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 Nandkumar, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182892

Device Name
TRAUS Dental Handpieces

Indications for Use *(Describe)*
The TRAUS Dental Handpieces, TRAUS CRB46LN and TRAUS CRB46NN are intended for a 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
3. Sinus elevation & grafting of alveolar sockets

D. Removal and sectioning of teeth and teeth bone for e.g. impacted third molars and complicated extractions

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.

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42921, Korea
Tel: +82 53 587 2345 / Fax: +82 53 580 0939

510(k) Summary

[As required by 21 CFR 807.92]

1. 510(k) Number

K182892

2. Date Prepared [21 CFR 807.92(a)(1)]

November 20, 2019

3. Submitter's Information [21 CFR807.92(a)(1)]

- Name of Applicant: Saeshin Precision Co., Ltd.
  - Address: # 52, Secheon-ro 1-gil, Dasa-eup, Dalseong-gun, Daegu, 42921, Republic of Korea
- Contact Name: Jong Woo, Choi (Mr.) / Quality Manager
  - Telephone No. : +82 53 587 2345
  - Fax No. : +82 53 580 0939
  - Email Address : ksqc@saeshin.com
- Registration Number: 3007958831

4. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: TRAUS Dental Handpieces
- Classification Name: Dental Handpieces and Accessories
- Common Name: Handpiece, Contra- And Right-Angle Attachment, Dental
- Classification Panel: Dental
- Classification Regulation: 21 CFR 872.4200
- Product Code: EGS
- Device Class: I

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5. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follows:

- 510(k) Number: K171436
- Applicant: Saeshin Precision Co., Ltd.
- Common Name: Dental Handpieces and Accessories
- Device Name: STRONG Dental Handpieces

There are no significant differences between the Model TRAUS Dental Handpieces and the predicate device. It is substantially equivalent to these devices in device design, composition of materials and technical specifications.

6. Description of the Device [21 CFR 807.92(a)(4)]

The TRAUS Dental Handpieces; TRAUS CRB46LN and TRAUS CRB46NN are gear driven hand-held dental handpieces with Gear Ratio of 20:1. They can be driven by torque adjustable electrical motors for surgery treatment. They are attached to drive via ISO 3964 coupling. The head clamp accepts instrument complying with ISO 1797-1. They have contra-angle attachment intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

7. Indications for Use [21 CFR 807.92(a)(5)]

The TRAUS Dental Handpieces, TRAUS CRB46LN and TRAUS CRB46NN are intended for a 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
   3. Sinus elevation & grafting of alveolar sockets

D. Removal and sectioning of teeth and teeth bone for e.g. impacted third molars and complicated extractions

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8. Technological Characteristics [21 CFR 807.92(a)(6)]

		TRAUS CRB46LN	TRAUS CRB46NN
Revolu-tion	**Max Speed in Rpm**	40,000 rpm	40,000 rpm
	After the gear speed reduction	2,000 rpm	2,000 rpm
Gear Ratio		20:1	20:1
Weight		approx.87g	approx.88g
Size		Ø20 x 94.8mm	Ø20 x 94.8mm
Articles		Low speed angle	Low speed angle
Standard Coupling		ISO 3964	ISO 3964

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9. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

When compared to the predicate device (K171436), the STRONG Dental Handpieces presented in this submission has the same:

- Indications for Use
- Device Design
- Composition of materials
- Technical Specifications

Parameter	**Proposed** **TRAUS Dental Handpieces (Model Nos.: TRAUS CRB46LN, TRAUS CRB46NN)**	**Predicate** **STRONG Dental Handpieces (Model Nos.: ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I, ACL(B)-04C)**
510(k) Number	Unknown	K171436
Manufacturer	Saeshin Precision Co., Ltd	Saeshin Precision Co., Ltd.
Indications for Use	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	The Strong 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

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52, Secheon-ro 1-gil, Dasa-eup, Dalseong-gun, Daegu, 42921, Korea
Tel: +82 53 587 2345 / Fax: +82 53 580 0939

Parameter	Proposed TRAUS Dental Handpieces (Model Nos.: TRAUS CRB46LN, TRAUS CRB46NN)	Predicate STRONG Dental Handpieces (Model Nos.: ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I, ACL(B)-04C)
	D. Removal and sectioning of teeth and teeth bone for e.g. impacted third molars and complicated extractions	bone for e.g. impacted third molars and complicated extractions
Device Design		
Operational Mode	Gear	Gear
Gear Ratio	20:1	20:1, 16:1, 64:1, 32:1, 1:1
Length	94.8 mm	96.9, 96.9, 99.5, 96.9, 83.3 mm
Diameter	Ø 20	Ø 19.6
Dia. of tool	2.35 mm	2.35 mm
Max. Overall Length of Rotary Instrument	30 mm	30 mm
Head Height	14 mm	14.45,14.2 mm
Head Diameter	Ø 9.6 mm	Ø 8, Ø 7.7 mm
Shank	By ISO 1797-1	By ISO 1797-1
Length of Shank	9 – 12 mm	9 – 12 mm
Type of Chuck	Push-Button Locking	Push-Button Locking
Coupling Dimension	By ISO 3964	By ISO 3964
Type of Connector	Not Applied	Not Applied
Accessories	Spray Nozzle	Spanner
Composition of Materials /Surface treatment		
Gear	SUS420F/Vacuum Heat Treatment	SUS420F/Vacuum Heat Treatment
Shank	N/A	SUS304
Head and Nozzle	SUS303F/Hard Chrome coated	SUS303F/Hard Chrome coated
Chuck	SUS420F/Vacuum Heat Treatment	SUS420F/Vacuum Heat Treatment
Handle	SUS303F/Hard Chrome coated	AL6061/Anodizing
Pipe	SUS304/Hard Chrome coated	SUS303F/Hard Chrome coated N/A (ACL(B)-04C)
Patient-Contacting	Chuck, Head	Chuck, Head
Operator-Contacting	Handle, Head	Handle, Head
Technical Specification		
Chuck Design	Type1 Push-Button Locking by ISO 1797-1	Type1 Push-Button Locking by ISO 1797-1

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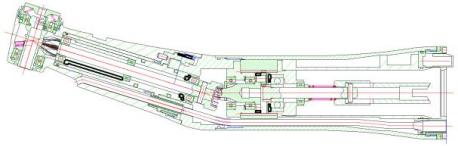
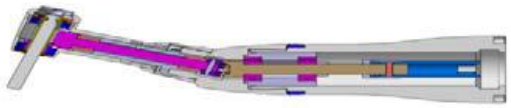
Parameter	Proposed TRAUS Dental Handpieces (Model Nos.: TRAUS CRB46LN, TRAUS CRB46NN)	Predicate STRONG Dental Handpieces (Model Nos.: ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I, ACL(B)-04C)
Bur Extraction Force(N) Max. Torques Max. Water Pressure Max. Speed in rpm Shank Conformance Coupling Dimension	45 N 80 Ncm N/A 40,000 rpm By ISO 1797-1 By ISO 3964	45 N 50 Ncm N/A 50,000 rpm, 35,000 rpm By ISO 1797-1 By ISO 3964
Lubricant Chemical Composition 510k# Biocompatible Delivery system	N/A	N/A
Sterilization	Steam Heat 132℃ / 4minutes	Steam Heat 132℃ / 4minutes
Operating principle	 The TRAUS Dental Handpieces are gear driven hand-held dental handpieces with gear ratio of 20:1. It can be driven by torque adjustable electrical motors for surgery treatment. It is attached to drive via ISO 3964 coupling. The head clamp accepts instrument complying with ISO 1797-1. They have contra angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.	 The STRONG Dental Handpieces are gear driven hand-held dental handpieces with gear ratio of 20:1, 16:1, 64:1, 32:1 and 1:1. It can be driven by torque adjustable electrical motors for surgery treatment. It is attached to drive via ISO 3964 coupling. The head clamp accepts instrument complying with ISO 1797-1. They have contra angle attachment for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

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10. Summary of Non-Clinical Performance Data

▮ Biocompatibility

Patient contact materials of the TRAUS Dental Handpieces are as follows:

1) TRAUS CRB46LN, TRAUS CRB46NN

Part	Material	Surface treatment	Patient contact	Duration of Contact by ISO 10993-1	Bio-compatibility
Head and nozzle	SUS303F	Hard Chrome Coated	Yes	Limited (<24 hours)	Yes
Chuck	SUS420F	Vacuum heat treatment	Yes	Limited (<24 hours)	Yes

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation per ISO 10993-10

▮ Bench Testing

The bench tests were performed in order to ensure the performance of the TRAUS Dental Handpieces; TRAUS CRB46LN and TRAUS CRB46NN verify conformity to ISO 14457 and demonstrate substantial equivalence to the predicates.

TRAUS CRB46LN and TRAUS CRB46NN samples were compliant with ISO 14457: 2017 Dentistry - Handpieces and Motors and demonstrated substantial equivalence to the predicates.

▮ Sterilization

The TRAUS Dental handpieces, TRAUS CRB46LN and TRAUS CRB46NN are provided nonsterile and labeled for sterilization by the end user, the Instructions for use include the following parameters:

Sterilization Type	Temperature	Time	Load Characteristics	Dry Time
Steam Sterilization (Pre-vacuum Type)	132 ℃	4 min.	Sterilization Bag	30 min.

The sterilization method was validated per :

- Reprocessing validation per the FDA Guidance Document entitled, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling” dated March 17, 2015
- Cleaning Process Validation per ASTM F2314 and ISO 15883-5
- Sterilization Validation per ISO 17665-1 and ISO 17665-2

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11. Conclusion [21 CFR 807.92(b)(3)]

In accordance with the Federal Food, Drug and Cosmetic, 21 CFR Part 807, and based on the information provided in this premarket notification Saeshin Precision Co., Ltd. Concludes that the TRAUS Dental Handpieces are substantially equivalent to predicate devices as described herein.