DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 1, 2015

Saeshin Precision Co., Ltd.
Mr. Sae Kwan Choi
Quality Manager
#52, Secheon-ro 1-gil, Dasa-eup, Dalseong-Gun
Daegu, 711-814
Republic of Korea

Re: K151171
Trade/Device Name: TRAUS SUS10
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone cutting instrument and accessories
Regulatory Class: II
Product Code: DZI, EGS, and EBW
Dated: July 30, 2015
Received: August 4, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
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)*

K151171

Device Name

TRAUS SUS10

Indications for Use *(Describe)*

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 implant surgery).

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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510(k) Summary

[As required by 21 CFR 807.92]

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

August 28, 2015

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: Saeshin Precision Co., Ltd.
  - Address: #52,Secheon-ro 1-gil, Dasa-eup, Dalseong-Gun, Daegu, 711-814, Repulic of Korea
- Contact Name: Sae Kwan Choi / Quality Manager
  - Telephone No. : +82 53-587-2341
  - Fax No. : +82 53-580-0999
  - Email Address : ksqc@saeshin.com
- Registration Number: 3007958831
- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

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

- Trade Name: TRAUS SUS10
- Common Name: Piezo Surgery and Implant Engine Unit
- Classification:

Classification Name:	Bone Cutting Instrument and Accessories
Classification Panel:	Dental
Classification Regulation:	21 CFR 872.4120
Product Code:	DZI, EGS, and EBW
Device Class:	II

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

The identified predicate devices within this submission are shown as follow;

Primary Predicate

- 510(k) Number: K121620
- Applicant: DMETEC Co., Ltd.
- Common Name: Ultrasonic Surgery
- Device Name: SmarThor

Reference Predicate

- 510(k) Number: K123695
- Applicant: Saeshin Precision Co., Ltd.
- Common Name: Dental Handpiece and Accessories
- Device Name: TRAUS SIP10

There are no significant differences between TRAUS SUS10 Piezo Surgery and Implant Engine Unit and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in device design, composition of materials, and technical specifications.

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

TRAUS SUS10, Piezo Surgery and Implant Engine Unit, combines the function of piezo surgery by using ultrasonic mechanical vibration and the function of dental implant motor surgery into one device.

TRAUS SUS10 includes a control box (main unit), foot controller and dental handpieces.

The dental handpieces of TRAUS SUS10 are supplied with two types:

- Piezo handpiece
- Dental implant motor handpiece incorporating an implant motor and an angle handpiece.

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 select options such as power (output intensity) and boost (vibration frequency), and for implant motor surgery mode which be able to select options such as speed, torque and gear ratio, and includes the memory function for input and output settings.

6. Intended Use [21 CFR 807.92(a)(5)]

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 implant surgery).

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

TRAUS SUS10, Piezo Surgery and Implant Engine Unit, combines the function of piezo surgery by using ultrasonic mechanical vibration and the function of dental implant motor surgery into one device.

The dental implant motor handpiece has been cleared by FDA (K123695, date – Dec. 18, 2012)

	Proposed Device	**Primary Predicate Device**	**Reference Predicate Device**
K Number	K151171	K121620	K123695
Model	TRAUS SUS10	SmarThor	TRAUS SIP10
Manufacturer	Saeshin Precision	DMETEC	Saeshin Precision
Intended Use	TRAUS SUS10 Piezo Surgery and Implant Engine Unit are 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	The device is intended for use in surgical procedures including osteotomy, osteoplasty, periodontal surgery and implantation	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.

	root canal preparation (for dental implant surgery).		
Design			
Component	Control box, Foot controller, Piezo handpiece, Implant motor, Angle handpiece	Control unit, Foot Switch, Ultrasonic handpiece, Tip	Control box, Foot controller, Implant motor, Angle handpiece
Handpiece	Piezo handpiece: TRAUS PEZ10XX Implant motor: TRAUS MBP10SX, TRAUS MBP10SL Angle handpiece: TRAUS CRB26LX, TRAUS CRB26XX, TRAUS CRB27LX, TRAUS CRB27XX	Ultrasonic handpiece	Implant motor: TRAUS MBP10SX, TRAUS MBP10SL Angle handpiece: TRAUS CRB26LX, TRAUS CRB26XX, TRAUS CRB27LX, TRAUS CRB27XX
Accessory	Motor stand, Hanger, Internal spray nozzle, Tube holder, Tube clamp, Power cord, Motor cap, Irrigation tube, Foot pole, Torque wrench, Tip holder, Sterilization Tray, Instruction manual, Spray nozzle, Spanner	Autoclave tray, Torque wrench, Hanger, Peristaltic pump tubing	Motor stand, Hanger, Internal spray nozzle, Tube holder, Tube clamp, Power cord, Motor cap, Irrigation tube, Foot hanger, Foot hanger joint cap, Y-connector

LED Light Intensity	25,000 Lux at 1 cm distance	N/A	25,000 Lux at 1 cm distance
Operation Mode	Ultrasonic mechanical vibration and Gear-driven	Ultrasonic mechanical vibration	Gear-driven
Operational Direction	Forward and Reverse	Not known	Forward and Reverse
Reduction Ratio	1:1, 16:1, 20:1, 27:1, 32:1, 64:1	Not known	1:1, 16:1, 20:1, 27:1, 32:1, 64:1
Coupling Dimension	ISO 3964	Not known	ISO 3964
Chuck Type	Push-button Locking	Not known	Push-button Locking
Shank Type	Type 1 (ISO 1797-1)	Not known	Type 1 (ISO 1797-1)
Water Port (for saline irrigation)	Yes	Yes	Yes
Hose Connection	Luer lock, dual connection One hose connected from irrigation pump to inlet of Piezo Handpiece and another hose from irrigation pump connected to Y-tube on Angle Handpiece	Luer lock, single connection Single hose connected from irrigation pump to inlet of ultrasonic surgical handpiece	Luer lock, single connection Single hose connected from irrigation pump to Y-tube on Angle Handpiece
Composition of Material			
Bur (in contact with patient)	Not provided.	N/A	Not provided.
Head and Nozzle (in contact with patient and operator)	Stainless steel	N/A	Stainless steel
Chuck (in contact with patient)	Stainless steel	N/A	Stainless steel
Handle (in contact with operator)	Stainless steel	N/A	Stainless steel
Tubing (in contact with patient and operator)	Silicon Rubber, Reference No. 32.F0244.00, OMNIA	Not known	Silicon Rubber, Reference No. 32.F0244.00, OMNIA

Technical Specification			
Supply Voltage	AC 100 - 120 V, 50/60 Hz	AC 100 - 240 V, 50/60 Hz	AC 100 - 120 V, 50/60 Hz
Sterilization	Autoclave	Autoclave	Autoclave
Bur Extraction Force(N)	Not less than 45 N	Not known	Not less than 45 N
Max. Torque	65 N·cm	Not known	65 N·cm
Max. Speed in rpm	40,000 rpm	Not known	40,000 rpm
Eccentricity	0.04 mm	Not known	0.04 mm
Output characteristics (Ultrasonic Mechanical Vibration)			
Maximum output power with load	48 W	50 W	N/A
Vibration frequency	24 to 30 kHz	24 to 32 kHz	N/A

Non-Clinical Test Summary:

1) Electrical Safety, Electromagnetic Compatibility and Performance:

TRAUS SUS10 complies with the electrical safety and electromagnetic compatibility requirements established by the standards AAMI ES60601-1 and IEC 60601-1-2.

Bench testing of the subject devices includes:

- Testing to confirm compliance with the safety requirements of standard AAMI ES60601-1
- Testing to confirm compliance with EMC requirements of standard IEC 60601-1-2

2) Software Validation:

TRAUS SUS10 contains MODERATE level of concern software. 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, on May 11, 2005.

3) Biocompatibility:

TRAUS SUS10 is supplied with the dental implant motor handpiece which has patient contact materials and are found to be biocompatible throughout previous FDA clearance (K123695, date - Dec. 18, 2012) as the materials and manufacturing process are identical to the company's own predicate device.

4) Sterilization Validation:

The handpieces of TRAUS SUS10 are not provided for the sterilization but are sterilized by the user prior to use. The sterilization of the handpieces was validated in accordance with the standard ISO 17665-1.

5) Mechanical Performance Testing

The TRAUS SUS10 is in compliance with ISO 14457:2012, Dentistry - Handpieces And Motors, and the following tests:

- Eccentricity
- Extraction Force
- Visual inspection of General Design
- Temperature Rise
- Resistance to Reprocessing
- Working Frequency
- Output Intensity Level
- Vibration Frequency Booster Level
- Torque
- Speed
- Irrigation Water Flow Rates

6) Clinical Test Summary:

No clinical studies were considered necessary and performed.

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

When compared to the predicate devices (K121620 and K123695), TRAUS SUS10 Piezo Surgery and Implant Engine Unit in this submission presented the same in terms of:

- Intended Use
- Device design
- Components and materials
- Technological characteristics
- Output characteristics

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

In according with the Federal Food & drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Saeshin Precision Co., Ltd. concludes that TRAUS SUS10 is substantially equivalent to predicate devices as described herein.