DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 31, 2015

Saeshin Precision Co., Ltd.
Choi Sae Kwan
Quality Assurance Manager
52 Secheon-ro 1-gil, Dasa-eup
Dalseong- gun, Daegu 711-814
KOREA

Re: K143418
Trade/Device Name: STRONG Dental Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental handpiece and accessories
Regulatory Class: I
Product Code: EGS
Dated: June 18, 2015
Received: June 22, 2015

Dear Choi Sae Kwan:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

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)*
K143418

Device Name
STRONG Dental Handpieces

Indications for Use *(Describe)*
The STRONG Dental Handpieces, ACL(B)-03C and ACL(B)-03F, 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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]

This 510(k) summary is prepared in accordance with 21 CFR807.92

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

10/28/2014

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

- Name of Sponsor: Saeshin Precision Co., Ltd.
  - Address: # 52, Secheon-ro 1-gil, Dasa-eup, Dalseong-gun, Daegu, 711-814, Republic of Korea
- Contact Name: Sae Kwan, Choi (Mr.) / 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: STRONG Dental Handpieces
- Common Name: Dental Handpiece and Accessories
- Classification Name: Dental Handpiece and Accessories
- Classification Panel: Dental
- Classification Regulation: 21 CFR 872.4200
- Product Code: EGS

- 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 follows:

- 510(k) Number: K100192
- Applicant: Saeshin Precision Co., Ltd.
- Common Name: Dental Handpieces and Accessories
- Device Name: STRONG Dental Handpieces

There are no significant differences between the proposed models of STRONG Dental Handpieces and the predicate device 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)]

The STRONG Dental Handpieces; ACL(B)-03C and ACL(B)-03F are gear driven hand-held dental handpieces with Gear Ratio of 1:1. 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 for difficult to reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

The STRONG Dental Handpieces are similar to other commercially available products based on intended use, material, design and use concept. And they also comply with ISO 3964 coupling and ISO 1797-1 shank.

Based on the comparison of intended use and technical features, the STRONG Dental Handpieces are substantially equivalent to the predicate devices

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

The STRONG Dental Handpieces, ACL(B)-03C and ACL(B)-03F, 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

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

	ACL(B)-03C	**ACL(B)-03F**
Revolution	0~35,000RPM	0~35,000RPM
Gear Ratio	1:1	1:1
Weight	approx. 45g	approx. 46g
Size	Ø19.6x 83.7mm	Ø19.6x 83.7mm
Articles	Low speed angle	Low speed angle
Standard Coupling	ISO 3964	ISO 3964

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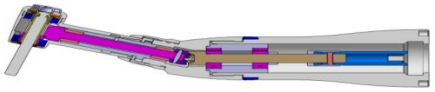
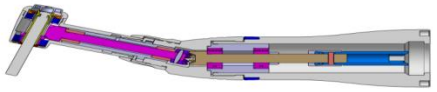
8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

When compared to the predicate device (K100192), the STRONG Dental Handpieces presented in this submission has the same:

- Intended Use
- Device Design
- Composition of materials
- Technical Specifications

Parameter	**Proposed** **STRONG Dental Handpieces (Model Nos.: ACL(B)-03C and ACL(B)-03F)**	**Predicate** **STRONG Dental Handpieces (Model Nos.: AT- II, ACL-01C, ACL-02C and ACL(B)-01C)**
510(k) Number	Unknown	K100192
Manufacturer	Saeshin Precision Co., Ltd	Saeshin Precision Co., Ltd.
The Indications for Use are the same in the predicate and proposed devices, except that the terms used in the predicate were clarified with plain English in the proposed device	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	The Strong Dental Handpieces are indicated for wide range of dental procedures. ● AT- II for the application in the area of the front teeth, root tip resection, bone removal, osteotomia on the upper and lower jaw, preprosthesis surgical modellation, sequestrotomia, fenestration on the alveolar appendix, apical ventilation, bone modellation, bone smoothing. ● ACL-01C, ACL-02C and ACL(B)-01C for the osteotomia on the upper and lower jaw, germectomia, sequestrotomia.

Parameter	Proposed STRONG Dental Handpieces (Model Nos.: ACL(B)-03C and ACL(B)-03F)	Predicate STRONG Dental Handpieces (Model Nos.: AT- II, ACL-01C, ACL-02C and ACL(B)-01C)
	D. Removal and sectioning of teeth and teeth bone for e.g. impacted third molars and complicated extractions	
Device Design		
Operational Mode	Gear	Gear
Gear Ratio	1:1	1:1
Length	83.7 mm	84.0, 84.0, 83.6 mm
Diameter	Ø 19.6	Ø 19.6
Dia. of tool	2.35, 1.60 mm	2.35 mm
Max. Overall Length of Rotary Instrument	30 mm	45, 30, 30 mm
Head Height	13.7 mm	13.7 mm
Head Diameter	Ø 8 mm	Ø 8, 10 mm
Shank	By ISO1797-1	By ISO1797-1
Length of Shank	9 – 12 mm	9 – 12 mm
Type of Chuck	Push-Button Locking	Latch or Push-Button Locking
Coupling Dimension	By ISO 3964	By ISO 3964
Type of Connector	Not Applied	Not Applied
Accessories	Spanner	Spanner
Composition of Materials /Surface Treatment		
Gear	SUS420F/Vacuum Heat Treatment	SUS420F/Vacuum Heat Treatment
Shank	SUS304	SUS304
Head and Nozzle	C3604BD-F/Hard Chrome Coated	C3604BD-F/Hard Chrome Coated
Chuck	SUS420F/Vacuum Heat Treatment	SUS420F/Vacuum Heat Treatment
Handle	AL6061/Anodizing	AL6061/Anodizing
Pipe	N/A	C3604BD-F
Patient-Contacting	Chuck, Head	Chuck, Head
Operator-Contacting	Handle, Head	Handle, Head
Technical Specification		

Parameter	Proposed STRONG Dental Handpieces (Model Nos.: ACL(B)-03C and ACL(B)-03F)	Predicate STRONG Dental Handpieces (Model Nos.: AT- II, ACL-01C, ACL-02C and ACL(B)-01C)
Chuck Design	Type1 and Type 3 Push-Button Locking by ISO 1797-1	Type 2 by ISO 1797-1 Type1 Latch or Push-Button Locking by ISO 1797-1
Bur Extraction Force(N)	45 N, 22N	55 - 56 N
Max. Torques	50 Ncm	50 Ncm
Max. Water Pressure	N/A	N/A
Max. Speed in rpm	35,000 rpm	30,000 - 35,000 rpm
Shank Conformance	By ISO 1797-1	By ISO 1797-1
Coupling Dimension	By ISO 3964	By ISO 3964
Lubricant Chemical Composition 510k# Biocompatible Delivery system	N/A	DO-ALL Dental Handpiece Lubricant K073353 N/A. Not intended for patient-contact Spray Nozzel
Sterilization	Steam Heat 132℃/4minutes	Steam Heat 134℃/4minutes
Operating principle	 The STRONG Dental Handpieces, ACL(B)-03C and ACL(B)-03F, are gear driven hand-held dental handpieces with gear ratio of 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	 The STRONG Dental Handpieces, AT- II, ACL-01C, ACL-02C and ACL(B)-01C, are gear driven hand-held dental handpieces with gear ratio of 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

Parameter	Proposed STRONG Dental Handpieces (Model Nos.: ACL(B)-03C and ACL(B)-03F)	Predicate STRONG Dental Handpieces (Model Nos.: AT- II, ACL-01C, ACL-02C and ACL(B)-01C)
	intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.	reach areas intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

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9. Summary of Non-Clinical Performance Data

- **Biocompatibility**

The materials contacting patients of chuck and the head were totally same and have been previously cleared by FDA through K100192 of predicate device, STRONG Dental Handpiece. The test report has been issued by Korea Testing & Research Institute, 7-6, Gomak-Ri, Wolgot-Myeon, Gimpo-Si, Gyunggi-Do, 415-871, Korea.

The categorization of contact was established under ISO 10993-1:2009-10-15. According to the recommendations in this standard and FDA Blue Book Memo #G95-1, the following tests are applicable and were performed:

- Cytotoxicity according to ISO 10993-5
- Sensitization according to ISO 10993-10
- Irritation or intracutaneous reactivity according to ISO 10993-10

- **Bench Testing**

Bench testing was performed to ensure the performance of the STRONG Dental Handpieces. ACL(B)-03C and ACL(B)-03F, verify conformity to ISO 14457 and demonstrate substantial equivalence to the predicates.

ACL(B)-03C and ACL(B)-03F samples were compliant with ISO 14457: 2012 Dentistry - Handpieces And Motors and demonstrated substantial equivalence to the predicates.

- **Visual inspection of general design**
  This test was performed with normal visual and profile projector. All the articles comply with the acceptance criteria of Section 7.2 of the handpiece standard.

- **Extraction force**
  The STRONG Dental Handpieces, ACL(B)-03C, for extraction test mandrel type 3 from the locking chuck system shall be at least 45N. In addition, STRONG Dental Handpieces, ACL(B)-03F, for extraction test mandrel type 5 from the locking chuck system shall be at least 22N. The results are reported in the table below;

Article No.	Mean (N)
ACL(B)-03C	51.2 N
ACL(B)-03F	32.2 N

- **Eccentricity**
  The eccentricity of the test mandrel in rotation and without applied load shall not be exceeded the total indicated run-out of 0.08 mm. The results are reported in the table below

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Article No.	Mean (mm)
ACL(B)-03C	0.014
ACL(B)-03F	0.012

- **Resistance to sterilizing procedure**
  After 250 cycles of 132℃ for 4 minutes in the autoclave, there was no sign of deterioration.

Article No.	Deterioration detected	Extraction > 45 N, > 22 N	Max. speed ±10% rpm	Noise < 70dB
ACL(B)-03C	No	51.2 N	35,120	55
ACL(B)-03F	No	32.2 N	35,090	54

- **Temperature rise**
  Rise of maximum temperature at the touchable surface of the housing under rated running conditions shall not exceed 20℃ compared to the temperature of the environment. The results are reported in the table below;

Article No.	Mean (℃)
ACL(B)-03C	10
ACL(B)-03F	6

- **Resistance to corrosion**
  Handpieces are corrosion resistant. There was no signs of corrosion after having autoclave procedure 10 times at 132℃ for 4 minutes at 22kPa.

- **Clinical and non-clinical tests**

A non-clinical evaluation, based on literature research, has been done. The evaluation of the applicable market data showed that STRONG Dental handpieces, ACL(B)-03C and ACL(B)-03F, do not pose known or new clinical risks than similar medical devices currently on the market. Based on those results clinical test have not been executed.

- **Sterilization**

The STRONG Dental handpieces, ACL(B)-03C and ACL(B)-03F, is provided non-sterile and labeled for sterilization by the end user, the Instructions for use include the following parameters:

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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 ISO 17665-1: 2006 Sterilization of health care products – Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

10. 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 Presicion Co., Ltd. Concludes that the STRONG Dental Handpieces are substantially equivalent to predicate devices as described herein.

In all the respects, the STRONG Dental Handpieces is the equivalent to currently marketed device.