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

January 5, 2018

Re: K171436
Trade/Device Name: STRONG Dental Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EGS
Dated: December 5, 2017
Received: December 5, 2017

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. 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.

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.
Acting 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)*
K171436

Device Name
STRONG Dental Handpieces

Indications for Use *(Describe)*
The STRONG Dental Handpieces, ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I and ACL(B)-04C 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.

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K171436

510(k) Summary
[As required by 21 CFR 807.92]

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

January 2, 2018

2. 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
-

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

- Trade Name: STRONG 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

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- Device Class: I

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: K143418
- Applicant: Saeshin Precision Co., Ltd.
- Common Name: Dental Handpieces and Accessories
- Device Name: STRONG Dental Handpieces,

There are no significant differences between the Model STRONG Dental Handpieces and the predicate device. 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)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I and ACL(B)-04C are gear driven hand-held dental handpieces with Gear Ratio of 20:1, 16:1, 64:1, 32:1 and 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 intended to prepare dental cavities for restorations, such as fillings, and for cleaning teeth.

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

The STRONG Dental Handpieces, ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I and ACL(B)-04C are intended for a wide range of dental procedures including:

A. Implant placement, including
   1. Preparation of the osteotomy site
   2. Bone contouring, osteoplasty

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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)-61I	ACL(B)-62I	ACL(B)-63I	ACL(B)-65I	ACL(B)-04C
Revolution	**Max Speed in Rpm**	50,000rpm	50,000rpm	50,000rpm	50,000rpm	35,000rpm
	After the gear speed reduction	2,500rpm	3,125rpm	781rpm	1,562rpm	35,000rpm
Gear Ratio		20:1	16:1	64:1	32:1	1:1
Weight		approx. 50g	approx. 50g	approx. 55g	approx. 50g	approx. 47g
Size		Ø19.6x 96.9mm	Ø19.6x 96.9m	Ø19.6x 99.5mm	Ø19.6x 96.9mm	Ø19.6x 83.3mm
Articles		Low speed angle	Low speed angle	Low speed angle	Low speed angle	Low speed angle
Standard Coupling		ISO 3964	ISO 3964	ISO 3964	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 (K143418) 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)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I, ACL(B)-04C)**	**Predicate** **STRONG Dental Handpieces (Model Nos.: ACL(B)-03C, ACL(B)-03F)**
510(k) Number	Unknown	K143418
Manufacturer	Saeshin Precision Co., Ltd	Saeshin Precision Co., Ltd.
Intended Use	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	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

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Parameter	Proposed STRONG Dental Handpieces (Model Nos.: ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I, ACL(B)-04C)	Predicate STRONG Dental Handpieces (Model Nos.: ACL(B)-03C, ACL(B)-03F)
	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	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
Device Design		
Operational Mode	Gear	Gear
Gear Ratio	20:1, 16:1, 64:1, 32:1, 1:1	1:1
Length	96.9, 96.9, 99.5, 96.9, 83.3 mm	83.7 mm
Diameter	Ø 19.6	Ø 19.6
Dia. of tool	2.35 mm	2.35, 1.60 mm
Max. Overall Length of Rotary Instrument	30 mm	30 mm
Head Height	14.45,14.2 mm	13.7 mm
Head Diameter	Ø 8, Ø 7.7 mm	Ø 8 mm
Shank	By ISO1797-1	By ISO1797-1
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	Spanner	Spanner
Composition of Materials /Surface treatment		
Gear	SUS420F/Vacuum Heat Treatment	SUS420F/Vacuum Heat Treatment
Shank	SUS304	SUS304
Head and Nozzle	SUS303F/Hard Chrome coated	C3604BD-F/Hard Chrome Coated
Chuck	SUS420F/Vacuum Heat Treatment	SUS420F/Vacuum Heat Treatment
Handle	AL6061/Anodizing	AL6061/Anodizing
Pipe	SUS303F/Hard Chrome coated	N/A

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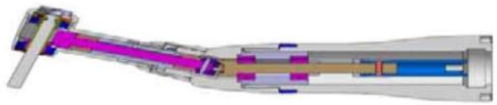
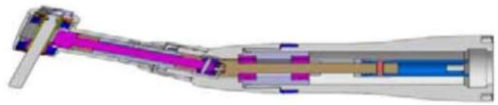
Parameter	**Proposed** **STRONG Dental Handpieces (Model Nos.: ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I, ACL(B)-04C)**	**Predicate** **STRONG Dental Handpieces (Model Nos.: ACL(B)-03C, ACL(B)-03F)**
	N/A (ACL(B)-04C)	
Patient-Contacting	Chuck, Head	Chuck, Head
Operator-Contacting	Handle, Head	Handle, Head
Technical Specification		
Chuck Design	Type1 Push-Button Locking by ISO 1797-1	Type1 and Type 3 Push-Button Locking by ISO 1797-1
Bur Extraction Force(N)	45 N	45 N, 22N
Max. Torques	50 Ncm	50 Ncm
Max. Water Pressure	N/A	N/A
Max. Speed in rpm	50,000 rpm, 35,000 rpm	35,000 rpm
Shank Conformance	By ISO 1797-1	By ISO 1797-1
Coupling Dimension	By ISO 3964	By ISO 3964
Lubricant		
Chemical Composition	N/A	N/A
510k#		
Biocompatible		
Delivery system		
Sterilization	Steam Heat 132℃/4minutes	Steam Heat 132℃/4minutes
Operating principle	 The STRONG Dental Handpieces, ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I and ACL(B)-04C 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	 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

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Parameter	Proposed STRONG Dental Handpieces (Model Nos.: ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I, ACL(B)-04C)	Predicate STRONG Dental Handpieces (Model Nos.: ACL(B)-03C, ACL(B)-03F)
	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.	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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9. Summary of Non-Clinical Performance Data

l Biocompatibility

The materials contacting patients of chuck, head and nozzle were totally same and have been previously cleared by FDA through STRONG Implant Handpieces (K092412) of predicate device, STRONG Dental Handpiece. The biocompatibility test report has been issued by Korea Testing & Research Institute, 7-6, Gomak-Ri, Wolgot-Myeon, Gimpo-Si, Gyunggi-Do, 415-871, Korea for the predicate is applicable to the subject device:

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

The device complies with the ISO10993-1 standard, and the materials contacting patients are biocompatible.

▌Bench Testing

The bench tests were performed in order to ensure the performance of the STRONG Dental Handpieces, ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I and ACL(B)-04C verify conformity to ISO 14457 and demonstrate substantial equivalence to the predicates.

ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I and ACL(B)-04C samples were compliant with ISO 14457: 2012 Dentistry - Handpieces And Motors and demonstrated substantial equivalence to the predicates.

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▌Sterilization

The STRONG Dental handpieces, ACL(B)-61I, ACL(B)-62I, ACL(B)-63I, ACL(B)-65I and ACL(B)-04C 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

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.