September 19, 2022

Saeyang Microtech Co., Ltd.
% DongHa Lee
RA Consultant
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SOUTH KOREA

Re: K213897
Trade/Device Name: Pro M Class
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: June 16, 2022
Received: June 21, 2022

Dear Yeon 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,

Michael E. Adjodha, M. ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K213897

Device Name

PRO M CLASS

Indications for Use *(Describe)*
The PRO M CLASS is used by dental professionals for orthodontic and endodontic procedures using a root canal instrument and tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.

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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V. 510(k) Summary (K213897)

This summary of 510(K) - substantial equivalence information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: June 16, 2022

1. Applicant / Submitter

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3. Device

- Trade Name: PRO M CLASS
- Common Name: AC-Powered Direct Drive Handpiece
- Classification Name: Dental handpiece and accessories
- Classification Product Code: EKX
- Classification Regulation: 21 CFR 872.4200
- Device Class: Class I

4. Predicate Device

- **Predicate Devices:**
  (K111616) E-CUBE

- **Reference Devices:**
  (K161500) MEG-TORQ
  (K110278) Cordless Prosthodontic Screwdriver with Torque Calibration System, Model iSD900

5. Description

- **General**

  The PRO M CLASS is an AC-powered device that includes a 'Motor Handpiece', 'Contra angle Handpiece', 'Charger unit' and 'AC/DC Adaptor' for grinding, cutting, polishing and screw driver work in dental oral use.

  [Note] The Dental Bur is not provided with the subject device.

- **Technological Characteristics**

  The PRO M CLASS uses the battery inside the motor handpiece as a power source to rotate the micromotor to transmit the generated rotational power to the contra angle. Dental treatment is performed using the rotational power obtained by this.

- **Principle of Operation**

  The motor turned by the power converted into DC 5.0V by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated, stopped and set/adjusted on/in its speed, torque and turning direction by handling of the controller.

6. Indication for use

The PRO M CLASS is used by dental professionals for orthodontic and endodontic procedures using a root canal instrument and tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.

7. Basis for Substantial Equivalence

The PRO M CLASS is substantially equivalent to the predicate device in terms of intended use, technical & performance characteristic, electrical power, design, and function.

Also, the Indications for Use for the subject devices is identical to the predicate device (K111616) for endodontic and orthodontic procedure in dental oral use, and the reference devices (K161500, K110278) for screw-driver function in dental implant in prosthodontic treatment.

The electrical safety and performance testing performed on the subject device demonstrate that the difference in external design and some technological characteristics compared predicate device does not raise any new issues.

The sterilization validation performed on the subject device demonstrates that the difference in sterilization method does not raise any new issues. Any of difference (chuck design and lubricant) also does not raise any new issues of safety and effectiveness as compared to the predicate device.

Based on the comparison charts below and test results provided in this submission, we conclude that the subject device is substantially equivalent to the predicate device.

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Comparison
510(k) No.	Not yet	K111616	K161500	K110278	-
Device Name	PRO M CLASS	E-CUBE	MEG-TORQ	Cordless Prosthodontic Screwdriver with Torque Calibration System, Model iSD900	-
Manufacturer	Saeyang Microtech Co., Ltd.	Saeshin Precision Co., Ltd.	MICRO-NX Co., Ltd.	Nakanishi, Inc.	-
Regulation Number	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	21 CFR 872.4200	Same
Product Code	EKX	EKX	EKX	EKX	Same
Regulatory Class	Class I	Class I	Class I	Class I	Same
Use	RX only	RX only	RX only	RX only	Same
Indications for Use Statement	The PRO M CLASS is used by dental professionals for orthodontic and endodontic procedures using a root canal instrument and tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.	The E-CUBE is indicated for use by dentists in standard endodontic procedures using rotary endodontic files and rotary endodontic drills (Gates-Glidden).	This product is a cordless motor handpiece system intended for tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.	This product is a cordless motor handpiece system intended for tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment.	Similar [1)]
Component	Contra-Angle Handpiece Motor Handpiece Charger Adapter	Contra-Angle Handpiece Motor Handpiece Controller, Adapter	Contra-Angle Handpiece Motor Handpiece Charger Adapter	Contra-Angle Handpiece Motor Handpiece Charger	Same
Operational Mode	Speed control, Torque control, Rotate both forward/reverse operation	Speed control, Torque control, Rotate both forward/reverse operation	Speed control, Torque control, Rotate both forward/reverse operation	Speed control, Torque control, Rotate both forward/reverse operation	Same
Principle of Operation	The motor turned by the power converted into DC voltage by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated stopped and set/adjusted on/in its speed, torque and turning direction by handling of the controller.	The motor turned by the power converted into DC voltage by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated stopped and set/adjusted on/in its speed, torque and turning direction by handling of the controller.	The motor turned by the power converted into DC voltage by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated stopped and set/adjusted on/in its speed, torque and turning direction by handling of the controller.	The motor turned by the power converted into DC voltage by controller delivers its turning power to the file through spin to perform punching, cutting and removing functions. The hand-piece can be operated stopped and set/adjusted on/in its speed, torque and turning direction by handling of the controller.	Same
Electrical Safety	Complied with IEC 60601-1	Complied with IEC 60601-1	Complied with IEC 60601-1	Complied with IEC 60601-1	Same

Electromagnetic Compatibility	Complied with IEC 60601-1-2				Complied with IEC 60601-1-2		Complied with IEC 60601-1-2	Complied with IEC 60601-1-2	Same
Device Design – Motor Handpiece									
Battery Type	Li-Ion (DC 3.7 V, 800mAH)				None		Li-Polymer	Lithium (DC 2.4V, 0.3VA)	Different [2)]
Gear Ratio	1:1	4:1	-	-	1:1	4:1	-	-	Similar [3)]
Motor Speed (rpm)	2,000-10,000	500-2,500	-	-	13,000	3,250	-	-	
Motor Torque (Ncm)	-	-	-	-	-	1.3	-	-	
Gear Ratio	-	-	160:1	-	-	-	None	-	
Motor Speed (rpm)	-	-	15-70	-	-	-	15-60	-	
Motor Torque (Ncm)	-	-	5-35	-	-	-	5-35	-	
Gear Ratio	-	-	-	320:1	-	-	-	None	
Motor Speed (rpm)	-	-	-	15-25	-	-	-	15-25	
Motor Torque (Ncm)	-	-	-	10-40	-	-	-	10-40	
Device Design – Contra-Angle Handpiece									
Material (in contact with patient)	SUS303F, SUS420F (Head and Chuck)				SUS303F, SUS420F (Head and Chuck)		Unknown	Unknown	Same
Chuk Design	Type 1 by ISO 1797-1 Type 2 by ISO 1797-1 Type 3 by ISO 1797-1				Type 1 by ISO 1797-1		Type 1 by ISO 1797-1	Type 1 by ISO 1797-1	Same
Coupling Dimension	Complied with ISO 3964				Complied with ISO 3964		Complied with ISO 3964	Complied with ISO 3964	Same
Sterilization	Non-sterile (Autoclave by User at 135℃ for 3min.)				Non-sterile (Moist Heat by User at 132℃ for 4min.)		Non-sterile (Autoclave by User at 121℃ for 30min)	Non-sterile (Autoclave by User at 121℃ for 20min or at 132℃ for 15min)	Different [4)]
Device Design – Charger & Adapter									
Input	AC 100-240V, 50~60 Hz, 0.6A				AC 100-240V, 47-63Hz, 0.9-0.34A		AC 100 ~ 240V, 50~60 Hz, 0.3A	AC 100 ~ 240V, 50~60 Hz, 15VA	Different [5)]
Lubricant									
Legally-marketed lubricant (identify 510(k))	Pana-Spray made by NSK (K052700)				Unknown		Unknown	Unknown	Different [6)]

Substantial Equivalence Discussion
Discussion **Similar** [1)] The subject device has two main indications for use. The indications for use is based on the motor rotation speed and torque according to the gear ratio. First indication for use is for orthodontic and endodontic procedures is the same as the predicate device (K111616) Second indication for use is for tightening and loosening an abutment screw to fix and remove the abutment on a dental implant in prosthodontic treatment is the same as the reference devices (K161500, K110278). **Different** [2)] The motor handpiece is supplied power from the internal rechargeable battery and battery voltage is the different. The different was verified according to IEC 60601-1, IEC 80601-2-60 and IEC 62133-2. The testing results show that the difference does not raise any problems in the safety and effectiveness. **Similar** [3)] Motor rotation speed as 2,000-10,000 rpm (on gear ratio 1:1) and 500-2,500 rpm (on gear ratio 4:1) are for orthodontic and endodontic procedures. It is similar to the predicate device (K111616). Motor rotation speed as 15-70 rpm (torque 5-35 on gear ratio 160:1) is for prosthodontic treatment as tightening and loosening an abutment screw to fix and remove. It is similar to the reference device1 (K161500). Motor rotation speed as 15-25 rpm (torque 10-40 on gear ratio 320:1) is for prosthodontic treatment as tightening and loosening an abutment screw to fix and remove. It is the same as the reference device2 (K110278). Performance test (Bench test) according to ISO 14457 also was conducted. The testing results show that the difference does not raise any problems in the safety and effectiveness. **Different** [4)] The Sterilization method is slightly different from the predicate device (K111616). The sterilization was validated according to ISO 17665-1 and the differences in sterilization methods show that it does not raise any problems in the safety and effectiveness. **Different** [5)] The charger is supplied power from an AC/DC adapter. The power input of the AC/DC adapter is different from the predicate device (K111616). The different was verified according to IEC 60601-1, IEC 80601-2-60 and IEC 60601-1-2. The testing results show that the difference does not raise any problems in the safety and effectiveness. **Different** [6)] The subject device uses a legally-marketed lubricant (K052700). It has been evaluated and cleared by FDA about the safety and effectiveness. **Conclusion** The PRO M CLASS is substantially equivalent to the predicate device and the reference devices in terms of intended use, technical & performance characteristic and function. Also, the Indications for Use for the subject devices is identical to the predicate device (K111616) for endodontic and orthodontic procedure in dental oral use, and the reference devices (K161500, K110278) for screw-driver function in dental implant in prosthodontic treatment. The electrical safety and performance testing performed on the subject device demonstrate that the difference in some technological characteristics compared predicate device and reference devices does not raise any new issues.

The sterilization validation performed on the subject device demonstrates that the difference in sterilization method does not raise any new issues. Any of difference (lubricant) also does not raise any new issues of safety and effectiveness as compared to the predicate device.
Based on the comparison charts below and test results provided in this submission, we conclude that the subject device is substantially equivalent to the predicate device.