Premium Plus International Limited
Jessica Mao
QA Engineer
Flat 1001 Yuen Long Trading Centre, No. 33 Wang Yip Street West
Yuen Long, N.T.
Hong Kong, China

October 19, 2017

Re: K170261
Trade/Device Name: Premium Plus Prophy Air Motor
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EFB
Dated: September 11, 2017
Received: September 15, 2017

Dear Jessica Mao:

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 (DICE) 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" (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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170261

Device Name
Premium Plus Prophy Air Motor

Indications for Use *(Describe)*
The Premium Plus Prophy Air Motor is intended to be used with a disposable prophy angle and polishing paste by a trained dental clinician to perform dental prophylaxis.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

PREMIUM PLUS INTERNATIONAL LIMITED
Flat 1001 Yuen Long Trading Centre, No. 33 Wang Yip Street West, Yuen Long, HONG KONG
Phone: (852) 2761 3211, Facsimile: (852) 2761 3210, Email: jessicamao@premiumplushk.com

Section 5 510(k) Summary

[As Required by 21 CFR 807.92]

Revision date: Oct. 17, 2017

Submitter: Premium Plus International Limited
Flat 1001 Yuen Long Trading Centre,
No. 33 Wang Yip Street West,
Yuen Long, N.T. Hong Kong, China
(Establishment registration number: 3006847937)

Contact Person: Jessica Mao
QA Engineer
Tel: 852-27613211
Fax: 852-27613210
Email: jessicamao@premiumplushk.com

Trade/Device Name: Premium Plus Prophy Air Motor
Common Name: Dental Handpiece
Model Type: 1002-4
Device Panel: Dental
Basis for Submission: New Device
Regulation Name: Handpiece, Air-Powered, Dental
Device Classification: Class I
Regulation Number: 21 CFR 872.4200
Regulation Description: Dental Handpiece and Accessories
Product Code: EFB

Predicate Device to Premium Plus Prophy Air Motor:
Trade Name: Prophy Star 3 Hygiene Handpiece
510(k) Number: K070869
Manufactured by: DentalEz Inc., StarDental Division

Device Description:
Premium Plus Prophy Air Motor is a dental low speed prophy air motor with pneumatic rotor, scroll bearing, stainless steel inner parts and anodized aluminum body surface. With the impulse of air current supplied, it can drive a disposable prophy angle with polishing paste to polish teeth.

Indications for Use:
The Premium Plus Prophy Air Motor is intended to be used with a disposable prophy angle and polishing paste by a trained dental clinician to perform dental prophylaxis.

An electronic copy of the submission is being provided which is an exact duplicate of the paper copy.

PREMIUM PLUS INTERNATIONAL LIMITED

Flat 1001 Yuen Long Trading Centre, No. 33 Wang Yip Street West, Yuen Long, HONG KONG
Phone: (852) 2761 3211, Facsimile: (852) 2761 3210, Email: jessicamao@premiumplushk.com

Comparison of Technological Characteristics:

	Predicate Device	Subject Device	
Device	Prophy Star 3 Hygiene Handpiece (K070869)	Premium Plus Prophy Air Motor	/
Indications for Use	The prophy handpiece is used by trained dental professionals to perform dental prophylaxis	Premium Plus Prophy Air Motor is intended to be used with a disposable prophy angle and polishing paste by a trained dental clinician to perform dental prophylaxis.	Same
Target Users	Professional dentists and hygienists	Professional dentists and hygienists	Same
Location of Use	Dental offices	Dental offices	Same
Product Design	Metal housing (external casing) with internal drive shaft, gearings and chuck assembled and aligned to each other.	Anodized aluminum housing with internal drive shaft, gearings and chuck assembled and aligned to each other	Same
Dimensions & Weight:	Length 108.99 mm Diameter at handle 16.76 mm Weight 62 grams	Length 111.00 mm Diameter at handle 19 .00 mm Weight 69 grams	The subject device is a bit longer, bigger, and heavier than the predicate device.
Operating Air Pressure, Operating Speed and Power Output	Air Pressure 35-40 psi Operating Speed 0 to 5,000 rpm Power Output 5.8 Watts	Air Pressure 200kPa Operating Speed 0 to 2,480 rpm Power Output 6.0 Watts	Operating speed is different
Drive Mechanism	Chuck driven by pneumatic air rotor	Chuck driven by pneumatic air rotor	Same
Bio-compatibility	Made of non-toxic anodized aluminum	Biocompatibility tests were conducted in accordance with the requirements of ISO 10993-5 and ISO	Same

		10993-10. Test results indicate the subject device is non-cytotoxic, non-sensitizing and non-irritating.	
Compatibility with other dental devices	Designed to fit securely onto standard Mid-West style air hose connector and standard Doriot style prophy angles	Designed to fit securely onto standard 4-hole (mid-west style) connector and standard Doriot style prophy angles	Same
Sterility	Non-sterile	Non-sterile	Same
Mechanical Safety	Robust construction to withstand forces generated during cleaning cycle	Robust construction to withstand forces generated during cleaning cycle. The subject device passed the performance test in accordance with ISO 14457.	Same

Discussion of similarities and differences between the Proposed Device and the Predicate Device

In compare to the Prophy Star 3 Hygiene Handpiece, the Premium Plus Prophy Air Motor has the same indications for use, same target users and same location of use. They both have the same drive mechanism. They both have similar dimensions & weight, similar operating air pressure and similar power output. Furthermore, they both are non-sterile, bio-compatible, compatible with the same type of air hose connector and same type of disposable prophy angle, and both are mechanically safe.

Their operational speeds are different. The subject device's operational speed is within the extent of the predicate device's speed. The speed of the subject device conforms to the requirements of ISO 14457.

Performance Test:
The following tests were conducted to evaluate the functional performance and safety of Premium Plus Prophy Air Motor:

- ISO 14457:2012 Dentistry – Handpieces and Motors Test
- ISO 9168:2009 Dentistry – Hose Connectors for Air Driven Dental Handpieces Test

The test results confirm that Premium Plus Prophy Air Motor conforms to the requirements in ISO 14457:2012 and ISO 9168:2009, and is substantially equivalent for use as a dental prophy air motor.

PREMIUM PLUS INTERNATIONAL LIMITED

Flat 1001 Yuen Long Trading Centre, No. 33 Wang Yip Street West, Yuen Long, HONG KONG
Phone: (852) 2761 3211, Facsimile: (852) 2761 3210, Email: jessicamao@premiumplushk.com

Biocompatibility Test:

The following tests were performed to evaluate the biocompatibility of the device:

- Cytotoxicity per ISO 10993-5: 2009 Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity
- Oral Irritation per ISO 10993-10: Biological evaluation of medical device – Part 10: Tests for irritation and delayed –type hypersensitivity
- Sensitization per ISO 10993-10: Biological evaluation of medical device – Part 10: Tests for irritation and delayed –type hypersensitivity

Validation Testings:

Recommendations of the FDA Guidance on "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" were followed.

- Cleaning Validation - Protein Analysis
- Cleaning Validation – Hemoglobin Analysis
- Sterilization Validation – Gravity cycle 132 ℃ 15min
- Sterilization Validation – Gravity cycle 121 ℃ 30min
- Sterilization Validation – Prevacuum cycle 132 ℃ 4min

Conclusion

Based on the above analysis, Premium Plus International Limited believes that the Premium Plus Prophy Air Motor is Substantially Equivalent to the claimed predicate, that is the Prophy Star 3 Hygiene Handpiece.