February 24, 2021

W&H Dentalwerk Buermoos GmbH
Johann Scharl
Manager Regulatory Affairs
Ignaz Glaser Strasse 53
Buermoos, Salzburg AT - 5111
Austria

Re: K201703
Trade/Device Name: PROXEO Twist Cordless Polishing System PL-40 H
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: November 20, 2020
Received: November 27, 2020

Dear Johann Scharl:

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 Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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)*
K201703

Device Name

PROXEO Twist Cordless Polishing System PL-40 H

Indications for Use *(Describe)*

Battery driven electrical drive unit with wireless foot controller to perform cleaning and polishing of tooth surfaces and fillings.

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.

510(k) Summary

K201703

Submitter	W & H DENTALWERK BÜRMOOS GMBH Ignaz-Glaser-Strasse 53 A - 5111 Bürmoos Austria Tel.: 0043 -6274 / 6236 -297 Fax: 0043 -6274 / 6236 -55
Registration Number	9681479
Contact Person	Ing. Johann Georg SCHARL
Date of Preparation	Feb. 22, 2021
Device Name	PROXEO Twist Cordless Polishing System PL-40 H
Classification Name	Dental Handpiece and Accessories
Regulation Number	872.4200
Regulatory class	I
Product Code	EKX
Predicate Devices	Device Name: Young INFINITY Cordless Handpiece System 510(k) Number: K171377 (Decision Date: August 20th, 2018) Manufacturer: Young Dental Manufacturing Co.
Device Description	The “PROXEO Twist Cordless Polishing System PL-40 H” is an electrical drive unit for cleaning and polishing tooth surfaces and fillings by use of Disposable Prophy Angles, so-called “DPAs”. The system consists of - the cordless drive handpiece PL-40 H, - the wireless foot controller C-NW, - a handpiece holder, and - a charger inclusive adaptor. Its basic function is the conversion of electrical energy into a mechanical rotary motion. Power is supplied by a Li-ion battery, which is assembled in the drive handpiece and can be recharged by means of the provided charging cable. The battery is not changeable by the user. The device´s application is intended in dentistry.
Indications for Use:	Battery driven electrical drive unit with wireless foot controller to perform cleaning and polishing of tooth surfaces and fillings.

		New device	Predicate device	Judg-ment
Comparison: Technological Characteristics	Product Designation	PROXEO Twist Cordless Polishing System PL-40 H	Young INFINITY Cordless Handpiece System	different
	510k number	K201703	K171377	different
	Manufacturer	W&H Dentalwerk Buermoos GmbH Reg. No.: 9681479	Young Dental Manufacturing Co. Reg. No. 1941138	different
	Regulation Number	21 CFR 872.4200	21 CFR 872.4200	same
	Product Code	EKX	EKX	same
	Regulatory Class	Class I	Class I	same
	Use	RX only	RX only	same
	Indications for Use	Battery driven electrical drive unit with wireless foot controller to perform cleaning and polishing of tooth surfaces and fillings.	Battery driven electrical drive unit with wireless foot controller for use with disposable prophylaxis angles in hygiene operatory to perform cleaning and polishing of tooth surfaces and fillings.	equivalent
	appearance			equivalent (different marking)
	Handpiece drive	**PL-40 H**	(PL-40 H)	(same)
	Battery type:	Li-Ion	Li-Ion	same
	Runtime:	8 treatments with a polishing duration of 6 min.	8 treatments with a polishing duration of 6 min.	same
	Standby:	automatically after 4 min.	automatically after 4 min.	same
	Charging time:	approx. 2 h	approx. 2 h	same
	Rated voltage:	3,7 V	3,7 V	same
	Rated capacity:	680 mAh	680 mAh	same
	Max. speed:	3.000 rpm	3.000 rpm	same
	Maximum torque:	2 Ncm	2 Ncm	same
	Dimensions (W x D x H):	160 x 25 x 28 mm	160 x 25 x 28 mm	same
	Weight:	118 g	118 g	same

		New device	Predicate device	Judg-ment
Comparison: Technological Characteristics	**Foot control**	**C-NW**	(C-NW)	(same)
	Battery type:	Li-ion	Li-ion	same
	Runtime:	approx. 2 months	approx. 2 months	same
	Standby:	automatically if not actuated	automatically if not actuated	same
	Charging time:	approx. 3 h	approx. 3 h	same
	Rated voltage:	3.7 V	3.7 V	same
	Rated capacity:	680 mAh	680 mAh	same
	Dimensions (WxDxH):	117 x 117 x 38 mm	117 x 117 x 38 mm	same
	Weight:	190 g	190 g	same
	Charger:			
	Rated voltage:	100 - 240 V	100 - 240 V	same
	Permissible voltage fluctuation:	± 10 %	± 10 %	Same
	Frequency:	50 – 60 Hz	50 – 60 Hz	Same
	Power:	7 VA	7 VA	same
Comparison: New device versus Predicate device	The target field of application, the intended use, performance parameter and material are the same or, at least, quite similar to those of the predicate device. The differences are restricted to the devices´ labelling: the type designations and the devices´ as well as their manufacturers´ names are differently indicated on the products themselves, on their packaging, Instructions for Use, etc. Seen from the technological point of view, the products are identical. The above-mentioned differences do not have any negative effect on the substantial equivalence. Therefore, the new device is substantially equivalent to the predicate device.			

Non-clinical testing	Type testing according to ISO 14457:2017 “Dentistry – Handpieces and motors” Electrical Safety Tests according to IEC 80601-2-60:2012-02 “Medical electrical equipment – Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment” and IEC 60601- 1:2005, 3rd Ed. + Corr.1:2006 + Corr2:2007 as well as IEC 60601-1: 2012, 3.1 Ed. “Medical electrical equipment – Part: General requirements for safety” Electromagnetic Compatibility Test according to IEC 60601-1-2:2014 “Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements” and FCC 47CFR Part 15 C § 15.247 “Operation within the bands 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz” Safety Tests according to IEC 62133:2012 + Corr1:2013 “Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications” Software validation according to IEC 62304:2006 + A1:2015 “Medical device software – Software life-cycle processes”. Usability validation according to IEC 60601-1-6:2010 + A1:2015 “Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability” Biological Assessment / Cytotoxicity Testing according to ISO 10993-1:2009 + Cor 1:2010 “Biological evaluation of medical devices – Part 1: Evaluation and testing” and ISO 7405:2008 + A1:2013 “Dentistry – Evaluation of biocompatibility of medical devices used in dentistry”

Non-clinical testing	Reprocessing Tests under consideration of ISO 17664:2017 “Reprocessing of Health Care Products - Information to be provided by the manufacturer for the processing of medical devices” and ANSI/AAMI ST79:2010 + A1:2010 + A2:2011 + A3:2012 + A4:2013 “Comprehensive guide to steam sterilization and sterility assurance in health care facilities” as well as 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” Risk Assessment according to ISO 14971:2007. “Medical devices - Application of risk management to medical devices” Additionally, different further bench tests, such as material tests (reg. chemical resistance), life time tests, torque and functionality test and tests for ensuring the stability of packaging were performed house-internally and confirmed the product´s suitability for the use in practice.
Clinical Testing	Clinical performance testing was not conducted.
Conclusion	W&H considers the PROXEO Twist Cordless Polishing System PL-40 H to be substantially equivalent to the predicate device listed above. This conclusion is based on the similarities in intended use, principles of operation, functional design and structure. Differences between the devices shown in the comparison section above are minor and do not have any negative effect on equivalence.