December 17, 2021

Guilin Woodpecker Medical Instrument Co., Ltd.
% Yoyo Chen
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District
Shenzhen, Guangdong 518100
China

Re: K211531
Trade/Device Name: Cordless Prophy System, Model: i-Polish
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EKX
Dated: November 17, 2021
Received: November 29, 2021

Dear Yoyo Chen:

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,

For Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211531

Device Name
Cordless Prophy System, Model: i-Polish

Indications for Use *(Describe)*
i-Polish is a cordless prophylaxis handpiece equipped with control buttons and wireless foot control for use with disposable prophylaxis angles in hygiene operatory to perform cleaning and polishing procedures on teeth surface 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.

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510(k) Summary

This summary of 510(K) information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

1. Administrative Information

Submission Date	November 17, 2021
Manufacturer information	Guilin Woodpecker Medical Instrument Co., Ltd. Address: Information Industrial Park, Guilin National High-Tech Zone, Guilin, Guangxi, 541004, P.R. China Contact person: Ning Jiakang (宁加康) TEL: +86-773-2350532 FAX:+86-773-2350532 E-Mail: zmnbg03@glwoodpecker.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. 1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong Province, China. Contact person: Ms. Yoyo Chen E-Mail: yoyo@cefda.com; field@cefda.com
Establishment registration number	3005581016

2. Device Information

Type of 510(k) Submission:	Traditional
510 (k) number	K211531
Device Name:	Cordless Prophy System
Model:	i-Polish
Classification Name:	Handpiece, Direct Drive, Ac-Powered
Review Panel:	Dental
Device Class:	1
Regulation Number:	872.4200
Product Code:	EKX

3. Primary Predicate Device

Manufacturer	Young Dental Manufacturing Co 1, LLC
Device name	Young INFINITY Cordless Handpiece System
510(K) Number:	K171377
Regulation Description	Dental handpiece and accessories
Product Code	EKX

4. Reference Device

Manufacturer	Parkell Products Inc.
Device name	Low-Speed Prophy Handpiece
510(K) Number:	K983413
Regulation Description	Dental handpiece and accessories
Product Code	EKX

5. Device Description

The Cordless Prophy system is a cordless handpiece which is intended for use by dental professionals for cleaning and polishing teeth. This is a general hygiene procedure that is performed on people of all ages in a professional dental operatory.

The Cordless Prophy System is comprised of a cordless, battery-powered handpiece, a removable and autoclavable outer sheath, an AC powered battery charging station, a battery-powered wireless foot control and an AC adapter. Accessories to the Cordless Prophy System include three style of Disposable Prophy Angle (DPA), which is cleared as Class I, Product code ESG, under premarket notification K030603.
Additionally, the handpiece of Cordless Prophy System must be used with a Disposable Sleeve, which is cleared as Class II, Product Code PEM, under premarket notification K151123.

The handpiece features a removable outer sheath that is to be cleaned and steam sterilized prior to first use and after each patient use.

The i-Polish has two speed control mode for operation:

- **Foot control mode:** One is using it with the wireless foot control, where the amount of vertical actuation on the wireless foot control correlates to the speed of the handpieces supplied to the DPA, the corresponding variable speed range of the DPA is controlled and adjusted through varying pressure on the foot control. The adjustable range is 500 rpm to 4000 rpm;
- **Handpiece control mode:** And the other uses a Centralized control button located on the handpieces for six constant speed level, 500 rpm, 1000 rpm, 1500 rpm, 2000 rpm,

3000 rpm and 4000 rpm.

6. Intended use/Indication for use

i-Polish is a cordless prophylaxis handpiece equipped with control buttons and wireless foot control for use with disposable prophylaxis angles in hygiene operatory to perform cleaning and polishing procedures on teeth surface and fillings.

7. Comparison with Predicate Device

Items	**Subject Device (K211531)**	**Predicate Device (K171377)**	**Conclusion**
Product Code	EKX	EKX	Same
Class	1	1	Same
Regulation number	872.4200	872.4200	Same
Intended use/Indication for use	i-Polish is a cordless prophylaxis handpiece equipped with control buttons and wireless foot control for use with disposable prophylaxis angles in hygiene operatory to perform cleaning and polishing procedures on teeth surface 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.	Same
Use	Rx Only	Rx Only	Same
Handpiece geometry	Cylindrical shape with reverse radius geometry to aid in device handling. Tapered, swiveled nosecone area.	Cylindrical shape with reverse radius geometry to aid in device handling. Tapered, swiveled nosecone area.	Same
Handpiece power	Lithium-ion Battery capable of being recharged multiple times by inclusion of an AC/DC power supply.	Lithium-ion Battery capable of being recharged multiple times by inclusion of an AC/DC power supply.	Same
Foot control power	Foot control contains a Lithium-ion battery capable of being recharged multiple times by inclusion of AC/DC power supply.	Foot control contains a Lithium-ion battery capable of being recharged multiple times by inclusion of AC/DC power supply.	Same
Charge time	Handpiece: Approximately 2.5 hours Foot control: Approximately 2 hours	Handpiece: Approximately 2 hours Foot control: Approximately 3 hours	Different (Note 1)
Handpiece Dimension	27.6mm Dia×192mm	25mm Dia×156mm	Different (Note 2)

Items	Subject Device (K211531)	Predicate Device (K171377)	Conclusion
Prophy Angle Fit	The device could be fit with ***Disposable prophy angle which cleared under premarket notification K030603.***	Similar to most corded handpieces on the market today, our device will have a Doriot style nose which allows most prophy angles to be used on the device.	Different (Note 3)
Nose Cone (Also called as Outer Sheath in the subject device)	Outer sheath will swivel, the Outer sheath will also be removable and autoclavable for infection control.	Nose cone will swivel. The nosecone will also be removable and autoclavable for infection control.	Same
Infection Control/Sterilization Method	Outer sheath is to be to cleaned and sterilized prior to first use and after each patient. And the handpiece is to be covered with an FDA cleared Disposable Sleeve which is cleared as Class II, Product Code PEM, under premarket notification K151123.	Remove nosecone and sterilize via autoclave. The nosecose is to be cleaned and sterilized prior to first use and after each patient. Handpiece is to be covered with an FDA cleared Disposable Sleeve	Same
Lubrication Method	Lubricant Free Motor. Do not use Lubrication	Lubricant Free Motor. Do not use Lubrication	Same
User Interface on Handpiece	That handpiece will have a Centralized control button, which will enable connection to the foot control for activation.	That handpiece will have a power button, which will enable connection to the foot pedal for activation.	Same
Auto-off	The foot control and handpiece will automatically shut down if the standby time exceeds 5 minutes. The user would then have to press the Centralized control button to activate the handpiece again.	Handpiece will enter a standby mode if idle for more than 4 minutes. The user would then have to press the POWER button to activate the handpiece again.	Similar
Mode of Operation	Rotary	Rotary	Same
Speed Control	i-Polish has two speed control mode for operation. **Handpiece control mode:** Speed is controlled and adjusted through press the Centralized control button to achieve six constant speed level, 500 rpm, 1000 rpm, 1500 rpm, 2000 rpm, 3000 rpm and 4000 rpm.	Speed is controlled and adjusted through varying pressure on the foot pedal. The motor itself has a limit of 3000RPM (±10%).	Different (Note 4)

Items	Subject Device (K211531)	Predicate Device (K171377)	Conclusion
	Foot control mode: Speed is controlled and adjusted through varying pressure on the foot control. The adjustable range is 500 rpm to 4000 rpm.		
Speed Range (±10%)	500~4000 RPM	500-3000 RPM	Different (Note 4)
Maximum Torque (±10%)	1.2Ncm	1Ncm	Similar
Operating environment	Ambient temperature: +5°C ~ +40°C Relative humidity: 30% ~ 75% Atmospheric pressure: 70kPa ~106kPa	Ambient temperature: +10°C ~ +35°C; Relative humidity: 15% ~ 80%	Different (Note 5)
Transport and Storage Condition	Ambient temperature: -20°C ~ +55°C Relative humidity: 10% ~ 93% Atmospheric pressure: 70kPa ~106kPa	Ambient temperature: -20°C ~ +60°C; Relative humidity: 8% ~ 80%	Different (Note 5)
Compliance Standards	IEC 60601-1; IEC 60601-1-2; ISO 10993-5. ISO 10993-10. ISO 14457;	IEC 60601-1; IEC 60601-1-2; ISO 10993-5. ISO 10993-10. ISO 14457;	Same

Note 1: Charge time

Although the charge time of the subject device is different with predicate device, but the battery is complied with the IEC62133-2:2017 standard, Otherwise, the subject device has been demonstrated to comply with the requirements of electrical safety IEC 60601-1:2015. This difference will not raise any new safety and effectiveness issues.

Note 2: Handpiece Dimension

The handpiece dimension has a little bit difference with predicate device, but both products allow for similar interaction with the user. Otherwise, the dimension of subject device has been demonstrated to comply with the requirements of ISO14457-2017standard. This difference will not raise any new safety and effectiveness issues.

Note 3: Prophy Angle Fit

The subject device only could be fit with Disposable prophy angle which cleared under premarket notification K030603. The prophy angle fit does not impact the user experience during cleaning and polishing procedures. This difference will not raise any new safety and effectiveness issues.

Note 4: Speed Control, Speed Range

Although the speed of subject device could be controlled and adjusted through press the Centralized control button and varying pressure on the foot pedal. But both devices deliver similar torque and speed profiles.

The low-end speed limit(500RPM) is the same. The top speed (4000RPM) is much higher than the predicate device, but the top speed is still lower than a reference device K983413 (the claimed top speed is able to operate up to 5000 RPM). In addition, a comparison test carried out between subject device and predicate device to demonstrate the difference on the top speed will not arise new safety and effectiveness issues.

Otherwise, the subject device has been demonstrated to comply with the requirements of IEC 60601-1, ISO 80601-2-60, and IEC60601-1-2 standard requirement. The difference will not raise any new safety and effectiveness issues.

Note 5: Operating environment and Transport and Storage Condition

The difference will not raise new safety or effectiveness issue, because, the subject device has tested to conform with the IEC 60601-1 standard.

8. Non-Clinical Test Summary

8.1. Electromagnetic Compatibility and Electrical Safety Test

The subject device has passed safety testing in according to following standards.

1) IEC 60601-1:2005+AMD 1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2) IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3) IEC 80601-2-60 Edition 2.0 2019-06 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment
4) ISO 14457: 2017 Dentistry - Handpieces and motors
5) ANSI/IEEE C63.27:2017 American National Standard for Evaluation of Wireless Coexistence
6) FCC Rules and Regulations, Part 15, Subpart C
7) The rechargeable lithium battery has passed the IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.

8.2. Biocompatibility Test

The subject device has passed safety testing in according to following standards.

1) ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro

cytotoxicity

2) ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

9. Software Validation

Software documentation consistent with moderate level of concern is submitted in this 510(k). System validation testing presented in this 510(k) demonstrates that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels

10. Clinical Data

Substantial equivalence does not depend on the clinical test data.

11. Conclusion

The subject device is substantially equivalent to the primary predicate device (K171377). This conclusion is based upon comparison on indication for use, technological characteristics, and applicable safety standards. Any difference in the technological characteristics does not raise any new issues or concerns of safety or effectiveness.