Young Dental Manufacturing Co 1, LLC
Brian Prange
Sr. Engineer, New Product Development
13705 Shoreline Ct East
Earth City, Missouri 63045

August 20, 2018

Re: K171377
Trade/Device Name: Young INFINITY Cordless Handpiece System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EKX
Dated: July 19, 2018
Received: July 20, 2018

Dear Brian Prange:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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

7.1 Indications for Use Statement

Indications for Use

510(k) Number: K171377

Device Name: **Young INFINITY Cordless Handpiece System**

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.

Prescription Use ___ X ____ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

As required by the Safe Medical Devices Act (SMDA) of 1990 and in accordance with 21 CFR § 807.93, 510(k) summary is provided.

DATE: August 17, 2018

I. SUBMITTER

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III. 510(K) PREPARER

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IV. DEVICE

Brand Name of Device: Young INFINITY Cordless Handpiece System
Common or Usual Name: Handpiece, Direct Drive, AC Powered
Classification Name: Dental Handpiece and Accessories
Regulation: 21 CFR 872.4200
Device Classification: Class: I
Product Code: EKX

V. PREDICATE DEVICE

Trade Name: Midwest RDH Freedom Cordless Prophy System
Common Name: Prophy System
510(k) Number: K110753 (Decision Date: June 6, 2011)
Manufacturer: Dentsply International Inc.

VI. DEVICE DESCRIPTION

The proposed device, the Young INFINITY Cordless Handpiece System, is a cordless handpiece which is intended for use by a dental clinician during dental cleaning and polishing of tooth surfaces and fillings.

The Young INFINITY Cordless Handpiece System is comprised of a cordless, battery-powered handpiece, a removable nosecone, a cradle for the cordless handpiece, a direct current (DC) power supply and charging cord, and a wireless foot controller.

Accessories to the Young INFINITY Cordless Handpiece System include a single-use doriot style Disposable Prophy Angle (DPA), which can be purchased from any DPA manufacturer. Additionally, the Young Infinity Cordless Handpiece System must be used with a disposable barrier (cleared as Class II, Product Classification Code PEM, under premarket notification K151123 in 03/03/2016 as Cover-It™ Barrier Film).

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

The handpiece utilizes an on-board user control for on/off and an LED indicator to communicate handpiece battery life, handpiece battery charging, foot control low power level, excessive pressure being applied, and wireless pairing status. The handpiece can only be operated by the appropriately paired wireless foot controller.

The Young INFINITY Cordless Handpiece System is operated by using a wireless foot controller, where the amount of vertical actuation on the wireless foot controller correlates to the speed of the handpiece supplied to the DPA. The corresponding variable speed range of the DPA is between 500RPM and 3000RPM.

The wireless foot controller operates using a Bluetooth low energy (BLE) communication protocol. When the handpiece has been turned ON, engaging the wireless foot controller activates the (BLE) mode of both the cordless handpiece and the wireless foot controller. The wireless foot controller features LEDs to indicate when the BLE mode on the foot controller has been activated, battery charging and adequate battery power level.

VII. INDICATIONS FOR USE

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.

VIII. SUBSTANTIAL EQUIVALENCE

K110753: Midwest RDH Freedom Cordless Prophy System

Table 1. Device Comparison (Similarities and Differences)

Product Comparison – Similarities and Differences			
Characteristic	**Proposed Device**	**Midwest RDH Freedom Cordless Prophy System**	**Similarities & Differences**
Manufacturer	Young Dental	DENTSPLY	
510(k) Number	K171377	K110753	
Class	I	I	No difference
Regulation Number	872.4200	872.4200	No difference
Intended Use / Indications for Use	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.	The MIDWEST® RDH FREEDOM™ Cordless Prophy System is a high-performance cordless prophylaxis handpiece with a wireless foot pedal for use with Freedom disposable prophylaxis angles in a hygiene operatory to perform cleaning and polishing procedures on teeth.	No significant differences. Both devices have the same components, and are intended to clean and polish teeth. The proposed device has small differences in user population, but are more syntax than practical differences.
Product Code	EKX	EKX	No difference
Use	Rx Only	Rx Only	No difference
Handpiece geometry	Cylindrical shape with reverse radius geometry to aid in device handling. Tapered, swiveled nosecone area.	Cylindrical shape with tapered nosecone.	Both shapes are designed to fit in the user's hand
Handpiece Power	Lithium-Ion Battery capable of being re-charged multiple times by inclusion of an AC/DC power supply.	Lithium-Ion Battery capable of being re-charged multiple times by inclusion of an AC/DC power supply.	No difference
Handpiece Charge time	Approximately 2 hours	At least 90 minutes	Both products can be charged over night

Product Comparison – Similarities and Differences			
Characteristic	**Proposed Device**	**Midwest RDH Freedom Cordless Prophy System**	**Similarities & Differences**
Handpiece Dimensions	25mm Dia x 156mm	30mm Dia X 190mm length	Both products allow for similar interaction with the user.
Foot Pedal Power	Foot pedal contains a lithium ion battery capable of being re-charged multiple times by inclusion of AC/DC power supply.	Foot pedal contains a lithium ion battery capable of being re-charged multiple times by inclusion of AC/DC power supply.	No difference
Prophy Angle Fit	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.	Proprietary Disposable Prophy Angles that work exclusively with the system.	The prophy angle fit does not impact the user experience during cleaning and polishing procedures.
Nose Cone	Nose cone will swivel. The nosecone will also be removable and autoclavable for infection control.	Contains a removable, autoclavable outer sheath for infection control.	Both products aid users reprocessing

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Product Comparison – Similarities and Differences			
Characteristic	**Proposed Device**	**Midwest RDH Freedom Cordless Prophy System**	**Similarities & Differences**
Infection Control / Sterilization Method	Remove nosecone and sterilize via autoclave. The nosecose is to be cleaned and sterilized prior to first use and after each patient Do not sterilize the handpiece cradle, handpiece, or foot control. These devices may only be disinfected. The handpiece is to be covered with an FDA cleared disposable barrier sleeve.	Outer sheath is to be to cleaned and sterilized prior to first use and after each patient. Do not sterilize the inner module or charging station. These may be wiped with intermediate level disinfectants . The handpiece is to be covered with an FDA cleared disposable barrier sleeve.	Both products utilize a steam sterilization procedure for the removeable nosecone, and disinfection procedure for the handpiece.
Lubrication Method	Lubricant Free motor. Do not use lubrication.	Lubricant Free motor. Do not use lubrication.	No difference

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Product Comparison – Similarities and Differences			
Characteristic	**Proposed Device**	**Midwest RDH Freedom Cordless Prophy System**	**Similarities & Differences**
User Interface on Handpiece	That handpiece will have a POWER button, which will enable connection to the foot pedal for activation.	Handpiece does not have any user interface, and the handpiece is controlled exclusively by the cordless foot pedal.	Both devices have clear methods for turning the device ON
Auto-Off	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.	Handpiece will enter standby mode if idle for more than 1 minute Product goes into enhanced battery-saving mode after 1 week of non-use.	Both devices have clear methods for automatically turning the device OFF to save battery power. The timing of auto-off sequences does not impact use.
Mode of Operation	Rotary	Rotary	No difference
Speed Control	Speed is controlled and adjusted through varying pressure on the foot pedal. The motor itself has a limit of 3000RPM (±10%).	Speed is controlled and adjusted through varying pressure on the foot pedal.	No difference
Speed Range	500 - 3000 RPM (±10%)	3000 RPM MAX	The top speed is the same on both devices. The low end speed limit does not impact use.
Torque Range	1Ncm torque	10 mNm	Both devices deliver similar torque / speed profiles, and have very similar motors.

Product Comparison – Similarities and Differences			
Characteristic	**Proposed Device**	**Midwest RDH Freedom Cordless Prophy System**	**Similarities & Differences**
Temperature	10 - 35°C	10-40°C	Both devices utilize the same low-end temperature, and have high-end temperature ranges consistent with storage, transportation and use conditions in the field today
Humidity	8-80% RH	45-95% RH	Both devices have humidity ranges consistent with storage, transportation and use conditions in the field today
Handpiece	YES	YES	No difference
Foot Pedal	YES	YES	No difference
Handpiece Holding Station	YES	YES	No difference
Handpiece Sleeves	YES	YES	No difference

As indicated in Table 1, all relevant comparison items are very similar, and do not exhibit any changes that would impact intended use or the user experience.

IX. PERFORMANCE DATA DEMONSTRATING SUBSTANTIAL EQUIVALENCE

The Young INIFNITY Cordless Handpiece System has the same intended use and operating principles, with similar features, and functional and performance characteristics as the previously-cleared devices. The device is designed to comply with relevant federal and international safety and performance standards. Conformance to these standards, coupled with no changes in the Indications for Use and no change in the fundamental scientific technology demonstrates substantial equivalence to the predicate devices.

Non-Clinical Performance Data: Testing included verification of component specifications, speed and torque control, connectivity of handpiece / foot controller communication, battery life, noise testing, software validation, chemical compatibility of housing materials, sterilizability, biocompatibility, fluid ingress, and electrical equipment safety. Tests were also performed to compare the speed, torque, weight, and dimensions of the Young INFINITY cordless handpiece system to the Midwest RDH Freedom Cordless Prophy System. The following testing was conducted

- Sterilization/Cleaning validation activities per ISO 17665-1 and ISO 17665-2. Reprocessing assessment and validation per the FDA Guidance Document for Reprocessing Medical Devices in Heath Care Setting: Validation Methods and Labeling including evaluation of design/mitigation methods to prevent contamination of the internal motor.
- Electrical Safety testing per IEC 60601-1 and Electromagnetic Compatibility testing per IEC 60601-1-2.
- Biocompatibility validation activities per FDA Guidance Document for Use of ISO 10993-1. Cytotoxicity testing on the final finished manufactured device per ISO 10993-5.
- Risk Analysis (hardware and software) per ISO 14971
- Software documentation for software of moderate level of concern per the FDA Guidance Document Software Contained in Medical Devices
- Hardware Performance/Safety Verification/Validation activities including conformance to ISO 14457 Dentistry -- Handpieces and motors

The results of this performance testing, combined with design and intended use comparison with the predicate device, Midwest RDH Freedom Cordless system (K110753), support substantial equivalence to the predicate device.

X. SUMMARY OF SIMILARITIES AND DIFFERENCES

The intended use and indications for use of the proposed Young INFINITY Cordless Handpiece System are equivalent to the legally marked predicate device, Midwest RDH Freedom Cordless Prophy System. The fundamental scientific technology of the proposed device is unchanged from the legally marketed predicate devices. The predicate device and submitted device share similar design features including battery type, mode of operation, and speed range. The devices share similar methods of control systems and operation. The devices share similar performance specifications including RPM and energy type.

XI. CONCLUSIONS

The Young INIFNITY Cordless Handpiece System is substantially equivalent to the listed predicate device, Midwest RDH Freedom Cordless Prophy System. The new device has the same intended use and operating principles, with similar features, and functional and performance characteristics.

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