September 3, 2021

MicroP Technology (Taiwan), Inc.
Ina Lin
Official Correspondent
No.50, Zhongxiao 2nd St., East District, Chiayi City 60080, Taiwan (R.O.C)
Chiayi City, 60080
TAIWAN

Re: K202786
Trade/Device Name: Dental Low-speed Handpieces and Accessories
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EFB, EGS
Dated: August 18, 2021
Received: August 23, 2021

Dear Ina Lin:

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,
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)*
K202786

Device Name
Dental Low-speed Handpieces and Accessories

Indications for Use *(Describe)*
The Dental Low-speed Handpieces and Accessories are intended for the removal of carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

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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Chapter 5 - 510(k) Summary

5.1. Submitter

807.92(a) (1)

Submitter	MicroP Technology (Taiwan), Inc.
Address	No.50, Zhongxiao 2nd, East Dist., Chiayi City 60080, Taiwan (R.O.C.)
Contact Person	Ina Lin
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Date Prepared	April. 30, 2020

5.2. Subject Device

807.92(a)(2)

Trade Name	Dental Low-speed Handpieces and Accessories	
K-number	K202786	
Applicant	MicroP Technology (Taiwan), Inc.	
Classification Code & Name	EGS	Handpiece, Contra- And Right-Angle Attachment, Dental
	EFB	Handpiece, Air-Powered, Dental
Regulation Number	872.4200	
Device Class	I	

5.3. Predicate Devices

807.92(a)(3)

Primary Predicate Device	MDK handpieces - Low-speed handpieces
K-number	K141886
Applicant	MODERN KOREA Co., Ltd.
Classification Name	Dental Handpiece and Accessories
Regulation Number	21 CFR 872.4200
Classification Code	EFB
Device Class	1

Reference Device	Codent Low Speed Dental Handpieces and Accessories
K-number	K150798
Applicant	Codent Technical Industry Co., Ltd.
Classification Name	Dental Handpiece & Accessories
Regulation Number	21 CFR 872.4200
Classification Code	EGS
Device Class	I

Reference Device	PANA SPRAY Plus
K-number	K131014
Applicant	NSK AMERICA CORP.
Classification Name	Dental Handpiece and Accessories
Regulation Number	21 CFR 872.4200
Classification Code	EFB
Device Class	1

5.4. Reasons for Why We Choose These Predicate Devices

807.92(a)(3)

We chose the MDK handpieces - Low-speed handpieces to be our primary predicate device because our device is much more similar with this device. However, there are still some differences that we chose Codent Low Speed Dental Handpieces and Accessories to be our reference device. And we chose the PANA SPRAY Plus to be the predicate device because our device composition is similar with this device. For more details, please see our SE comparison table.

5.5. Device Description

807.92(a)(4)

The low-speed dental handpieces are hand-held instruments driven by air motor or electric motor and relevant gear mechanism, capable of high speed, which is integrated into the head of the handpiece and has a chucking device coaxial with a rotating spindle. The Halley Series includes several models of contra-angle handpieces, straight handpieces, and air motors.

The handpieces are intended to be used by well-trained professionals in the field of general dentistry. They are reusable and some have a fiber-optic light system. They are supplied with drive power, water spray, and light through the electric or air motors connected to the tube and dental units.

The low-speed handpieces are divided into 4 types: contra-angle handpieces and straight handpieces, with or without fiber-optic. The contra-angle handpieces with fiber optic have 2 models and those without fiber optic have 3 models. The straight handpieces with fiber optic have 1 model and those without fiber optic have 2 models.

The handpieces are mainly made of stainless steel and must be reprocessed by the user before first use and after each use.

The Halley spray is a special formulated lubricant for lubricating general handpieces and air-motors. The application ensures well performance and durability for high/low-speed handpieces and air motor.

5.6. Indications for Use

807.92(a)(5)

The *Dental Low-speed Handpieces and Accessories* is intended for the removal of carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

Halley spray is intended to be used during routine maintenance in order to lubricate Dental Handpieces (including high and low speed) and Dental Air Motors after cleaning and prior to sterilization.

5.7. Device Technological Characteristics

807.92(a)(6)

The *Dental Low-speed Handpieces and Accessories* is similar in the operating principle, technical data and performance to other low speed dental handpieces currently in the US commercial distribution. Examples of substantially equivalent devices include the MDK handpieces - Low-speed handpieces (K141886) and Codent Low Speed Dental Handpieces and Accessories (K150798). The following table is a comparison of the proposed device to the predicate devices.

The Halley spray is similar in the operating principle, technical data and performance to other lubrication spray product in the US commercial currently distribution. Example of substantially equivalent devices PANA SPRAY Plus. The following table is a comparison of the proposed device to the predicate device.

Table 5.1_Model List for Handpieces

REF.	ISO 14457	Ratio	Fiber Optic	Water Spray
G95	Contra-angle handpiece	1:5	No	4 holes
G95L	Contra-angle handpiece	1:5	Yes	4 holes
G25	Contra-angle handpiece	1:1	No	4 holes
G25L	Contra-angle handpiece	1:1	Yes	4 holes
G23	Contra-angle handpiece	1:1	No	External irrigation
G65	Straight handpiece	1:1	No	4 holes
G65L	Straight handpiece	1:1	Yes	4 holes
G63	Straight handpiece	1:1	No	External irrigation

Table 5.2_Model List for Air Motors

REF.	ISO 14457	Coupling	Hose Connector	Fiber Optic	Water Spray
G205-M4	Air motor	ISO 3964 Type E	4 holes (ISO 9168 Type 2)	No	External irrigation
G205-B2	Air motor	ISO 3964 Type E	2 holes (ISO 9168 Type 1)	No	External irrigation

Table 5.2_Model List for Lubricant Spay

REF.	Size	Volume
AHZZ009	Large	600 mL
AHZZ011	Small	300 mL

Table 5.4_General Specification for Handpieces

Product Type	Contra-angle Handpieces					Straight Handpieces		
Model	G95	G95L	G25	G25L	G23	G65	G65L	G63
Color Coding	Red		Blue					
Max Rotation Speed	200,000 rpm		40,000 rpm					
Gear Ratio	1:5 (Increasing)		1:1 (Direct Drive)					
Water Spray Type	Internal 4-hole spray				External irrigation	Internal 4-hole spray		External irrigation
Fiber Optic	N/A	Glass Rod	N/A	Glass Rod	N/A	N/A	Glass Rod	N/A
Water Consumption	>50 mL (0.1 MPa)							
Bur Type	FG Bur (EN ISO 1797-1 Type 3 Ø1.60mm)		CA Bur (EN ISO 1797-1 Type 1 Ø2.35mm)			HP Bur (EN ISO 1797-1 Type 2 Ø2.35mm)		
Chip Air Consumption	Min. 1.5 NL/min (0.2 MPa)							
Water Consumption	Min. 50 mL/min (0.2 MPa)							
Max. Working Part Diameter	Ø2.0 mm		Ø4.0 mm					
Transportation and Storage Environment	Temperature: -10 - 50°C Humidity: 10 - 85% Atmospheric Pressure: 500 - 1,060 hPa							

Table 5.5_General Specification for Air Motors

Model	G205-M4	G205-B2
Hose Connection Type	ISO 9168 Type 2 (Midwest 4 hole)	ISO 9168 Type 1 (Borden 2 hole)
Handpiece Connection Type	E-type (ISO 3964 compatible)	
Max Rotation Speed	25,000 rpm	
Breakdown Torque	2.0 Ncm	
Drive Air Pressure	0.20 – 0.28 MPa (2.0 – 2.8 kgf/cm2)	
Air Consumption	50±5 NL/min (0.25 MPa)	
Water Pressure	0.15 – 0.25 MPa (1.5 – 2.5 kgf/cm2)	
Chip Air Pressure	0.15 – 0.25 MPa (1.5 – 2.5 kgf/cm2)	
Coolant Water Supply	50 mL/min and more (0.25 MPa)	
Coolant Air Supply	1.5 NL/min and more (0.25 MPa)	
Water Spray Type	External Irrigation	
Use Environment	Temperature: 0 – 40 °C, Humidity: 30 – 75 %, Atmos. Pressure: 700 – 1,060 hPa	
Transportation and Storage Environment	Temperature: -10 – 50 °C, Humidity: 10 – 85 %, Atmos. Pressure: 500 – 1,060 hPa	

Table 5.6_General Specification for Lubricant Spray

Product Type	**Small Spray can**	**Large Spray can**
Volume	300 mL	600 mL
Propellant	Butane	
Content	White Mineral Oil, Ethyl Alcohol	
Color	Transparent	
Purpose	For lubrication of dental handpieces, contra-angles, turbines, heads and air motors	

Table 5.7_Comparison Table

Descriptive Information	Dental Low-speed Handpieces and Accessories	MDK Low-speed handpieces	Codent Low Speed Dental Handpieces and Accessories
510(k) Number	K202786	K141886	K150798
Indications for use	MicroP Dental Low-speed Handpieces and Accessories is intended for removing carious material, excess filling material, cavity and crown preparation, finishing tooth preparations and restorations, root canal preparations and polishing teeth. All the devices are designed for use by a trained professional in the field of general dentistry.	Simliar	Simliar
Operational Modes	Air-powered	Identical	Identical
Type of chuck	Push button	Push button, latch, screw, snap-on or tip-lock chuck options	Identical
Composition of Main Materials	Stainless Steel, Aluminum Alloy	Stainless Steel, Titanium	Identical
Operating pressure	36psi to 43 psi	Identical	Information not available
Motor Speed	Up to 25,000 rpm	Up to 20,000 rpm	Identical
Lubricant	MicroP Halley Spray	Pana-Spray made by NSK(K052700)	Information not available
Sterilization	Steam autoclave method	Identical	Identical
Compliance to Standards	Complied with ISO 10993-5, ISO 10993-10, ISO14457	Identical	Information not available

Table 5.8_Comparison Table of Spray

Descriptive Information	Halley Spray	PANA SPRAY Plus	SE Comparison
510(k) Number	K202786	K131014	
Indications for use	*Halley Spray* is intended to be used during routine maintenance in order to lubricate Dental Handpieces (including low speed and high speed) and Dental Air Motors after each patient use and prior to sterilization.	***PANA SPRAY Plus*** is a lubricant intended to be used during routine maintenance of dental and surgical handpieces after each patient use and prior to sterilization.	Similar
Components name/ Weight percentage (% w/w)			
Lubricant	10.0 - 20.0%	5.0 - 10.0%	Different
Ethanol	15.0 - 25.0%	25.0 - 35.0%	Different
Propellant	50.0 - 80.0%	45.0 - 75.0%	Different

5.8. Non-clinical Testing Summary

807.92(b) (1)

The *Dental Low-speed Handpieces and Accessories* was developed taking into consideration all applicable technical standards, internal specifications and FDA guidance documents. The *Dental Low-speed Handpieces and Accessories* in compliance with the applicable international and internal standards was verified through bench testings.

The following standards were considered:

	Version
• ISO 14457, Dentistry — Handpieces and motors	2017
• ISO 1797, Dentistry -- Shanks for rotary and oscillating instruments	2017
• ISO 5349-1, Mechanical vibration — Measurement and evaluation of human exposure to hand-transmitted vibration — Part 1: General requirements	2001
• ISO 9168, Dentistry — Hose connectors for air driven dental handpieces	2009
• IEC 62366, Medical devices — Application of usability engineering to medical devices	2007
• ISO 10993-1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process	2018
• ISO 10993-5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	2009
• ISO 10993-10, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	2010
• ISO 17664 Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices	2017
• ISO 17665-1 Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices	2006

5.9. Clinical Testing Summary

807.92(b)(2)

Clinical testing has not been performed.

5.10. Conclusion

807.92(b)(3)

Based upon the comparison of technological characteristics, demonstrated through bench testing and intended use, the *Dental Low-speed Handpieces and Accessories* is substantially equivalent to the predicate devices.