MicroP Technology (Taiwan), Inc.
Ina Lin
Official Correspondent
No.40, Junghe Tsuen, Minshiung Township
Chiayi County, 621 Taiwan

July 24, 2018

Re: K173943
Trade/Device Name: Dental High-speed Handpiece and Accessories
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I
Product Code: EFB
Dated: June 22, 2018
Received: June 25, 2018

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. 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.

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

# Chapter 4 - Indications for Use Statement

| | |
|---|---|
| 510(k) Number (if know) | **K173943** |
| Device Name | Dental High-speed Handpiece Halley Series |
| Indications for Use | The Dental High-speed Handpiece Halley Series 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. |

Prescription Use ____X____ (per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (per 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

# Chapter 5 - 510(k) Summary

**Submitter** **807.92(a) (1)**

| | |
|---|---|
| Submitter | MicroP Technology (Taiwan), Inc. |
| Address | No.40, Junghe Tsuen, Minshiung Township,<br>Chiayi County 62153, Taiwan (R.O.C.) |
| Contact Person | Ina Lin |
| Email | ina.lin@micro-p.com.tw |
| Telephone | +886-5-2268808 (Tel.)<br>+886-5-2266697 (Fax) |
| Date Prepared | June 25, 2018 |

**Subject Device** **807.92(a)(2)**

| | |
|---|---|
| Trade Name | Dental High-speed Handpiece Halley Series |
| K-number | K173943 |
| Applicant | MicroP Technology (Taiwan), Inc. |
| Classification Name | Handpiece, Air-powered, Dental |
| Regulation Number | 872.4200 |
| Classification Code | EFB |
| Device Class | I |

**Predicate Devices** **807.92(a)(3)**

| | |
|---|---|
| Predicate Device | MASTERtorque LUX 8900 L |
| K-number | K130560 |
| Applicant | KALTENBACH & VOIGT GMBH (KaVo) |
| Classification Name | Handpiece, Air-powered, Dental |
| Regulation Number | 872.4200 |
| Classification Code | EFB |
| Device Class | I |

| | |
|---|---|
| Reference Device | MDK handpieces |
| K-number | K141886 |
| Applicant | MODERN KOREA CO., LTD. |
| Classification Name | Handpiece, Air-powered, Dental |
| Regulation Number | 872.4200 |
| Classification Code | EFB |
| Device Class | I |

We chose KaVo's MASTERtorque LUX 8900 L to be our primary predicate device because our device is much more similar with this device. However, there is still some deficiencies that we chose MDK handpieces to be our reference device. For more details, please see the comparison table in the document FDA01-12_Substantial Equivalence Discussion.

**Device Description** **807.92(a)(4)**

The *Dental High-speed Handpiece Halley Series* is a hand-held instrument which propelled by a small air-powered turbine (or rotor), capable of high speed, which is integrated into the head of the handpiece and has a chucking device coaxial with the turbine. The main materials of the dental handpiece and accessories are stainless steel. Rotation speed range is around 330,000-390,000 rpm. Our couplings are in compliance with the Type 1, Type 2 or Type 3 of the recognized standard ISO 9168 Hose connectors for air driven dental handpieces, and vary with the most famous brands in the world. For our device, there was no any other previous 510(k) clearance before this submission.

**Indications for Use** **807.92(a)(5)**

The *Dental High-speed Handpiece Halley Series* 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.

**Device Technological Characteristics** **807.92(a)(6)**

The *Dental High-speed Handpiece Halley Series* is similar in the operating principle, technical data and performance to other high speed dental handpieces currently in the US commercial distribution. Examples of substantially equivalent devices include the MASTERtorque LUX 8900 L (K130560) and MDK handpieces (K141886). The following table is a comparison of the proposed device to the predicate devices.

**General Specification**

| Head Size | Miniature | Standard | Torque |
|---|---|---|---|
| Rotation Speed | 330,000-~390,000 min (at the recommended drive air pressure.) | | 310,000-~370,000 min (at the recommended drive air pressure.) |
| Bur Type | ISO 1797-1Ø 1.59 ~ 1.60 mm Standard Bur | | |
| Max. Bur Length | 21 mm | | |
| Max. Working Part Diameter | Ø 2 mm | | |
| Recommended Drive Air Pressure | 40 psi | | |
| Operating Drive Air Pressure Range | 36~43 psi | | |
| Max. Air Consumption | < 66 NL/min | | |
| Water Pressure | 11~29 psi | | |
| Chip Air Pressure | 14~29 psi | | |
| Optic | Glass Rod | | |
| Use Environment | Temperature: 10~40°C (No Condensation),Humidity: 30~75% | | |
| Transportation and Store Environment | Temperature: -2~50°C, Humidity: 10~55%, Atmospheric Pressure:500~1060hPa | | |

**A001~A039 Model Specification Comparison**

| REF. | Head Size | Fiber Optic | Coupling | ISO 9168 | Holes |
|---|---|---|---|---|---|
| A001 | M | N | M4 type | Type 2 | 4 |
| A002 | S | N | M4 type | Type 2 | 4 |
| A003 | T | N | M4 type | Type 2 | 4 |
| A004 | M | N | NSK QDJ type | Type 2 | 4 |
| A005 | S | N | NSK QDJ type | Type 2 | 4 |
| A006 | T | N | NSK QDJ type | Type 2 | 4 |
| A007 | M | Y | NSK-PTL type | Type 3 | 6 |
| A008 | S | Y | NSK-PTL type | Type 3 | 6 |
| A009 | T | Y | NSK-PTL type | Type 3 | 6 |
| A010 | M | N | NSK-FM type | Type 2 | 4 |
| A011 | S | N | NSK-FM type | Type 2 | 4 |
| A012 | T | N | NSK-FM type | Type 2 | 4 |
| A013 | M | Y | KaVo Mutiflex type | Type 3 | 6 |
| A014 | S | Y | KaVo Mutiflex type | Type 3 | 6 |

| | | | | | |
|---|---|---|---|---|---|
| A015 | T | Y | KaVo Mutiflex type | Type 3 | 6 |
| A016 | M | N | KaVo Mutiflex type | Type 2 | 4 |
| A017 | S | N | KaVo Mutiflex type | Type 2 | 4 |
| A018 | T | N | KaVo Mutiflex type | Type 2 | 4 |
| A019 | M | Y | Sirona type | Type 3 | 6 |
| A020 | S | Y | Sirona type | Type 3 | 6 |
| A021 | T | Y | Sirona type | Type 3 | 6 |
| A022 | M | N | Sirona type | Type 2 | 4 |
| A023 | S | N | Sirona type | Type 2 | 4 |
| A024 | T | N | Sirona type | Type 2 | 4 |
| A025 | M | Y | W&H roto quick type | Type 3 | 6 |
| A026 | S | Y | W&H roto quick type | Type 3 | 6 |
| A027 | T | Y | W&H roto quick type | Type 3 | 6 |
| A028 | M | N | W&H roto quick type | Type 2 | 4 |
| A029 | S | N | W&H roto quick type | Type 2 | 4 |
| A030 | T | N | W&H roto quick type | Type 2 | 4 |
| A031 | M | N | B2 type | Type 1 | 2 |
| A032 | S | N | B2 type | Type 1 | 2 |
| A033 | T | N | B2 type | Type 1 | 2 |
| A034 | M | Y | Star type | Type 2 | 5 |
| A035 | S | Y | Star type | Type 2 | 5 |
| A036 | T | Y | Star type | Type 2 | 5 |
| A037 | M | N | Star type | Type 2 | 4 |
| A038 | S | N | Star type | Type 2 | 4 |
| A039 | T | N | Star type | Type 2 | 4 |

**# Note:**

| Head size | Fiber optic |
|---|---|
| M: Miniature<br>S: Standard<br>T: Torque | Y: Yes<br>N: No |

**Summary Table of Technological Characteristics**

| Characteristic | Subject Device | Reference Device | Predicate Device |
|---|---|---|---|
| Device name | Dental High-speed Handpiece Halley Series | MASTERtorque LUX 8900 L | MDK handpieces |
| K-number | K173943 | K130560 | K141886 |
| **Indications for use** | | | |
| Indications for use | The *Dental High-speed Handpiece Halley Series* 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. | Identical | MDK handpieces are used for the removal of carious material, reducing of hard tooth structure, cavity and crown preparations, removal of fillings, processing and finishing tooth preparations, restorations, and for polishing teeth. All the devices are designed for use by a trained professional in the field of general dentistry. |
| **Device design** | | | |
| Operational modes | Through the tubes | Identical | Identical |

| | | | |
|---|---|---|---|
| | connected to a dental unit, the air-powered handpiece receives the air for rotation, the cooling water and light for illumination of the operation area. | | |
| Air/water ports | 4 holes | Identical | Identical |
| Fiber optics | Y/N | Identical | Identical |
| Head dimensions | Height: 13.1 mm<br>Diameter:11.2 and 12.2 mm | Height: 13.0 mm<br>Diameter:12.5 mm | Not mentioned |
| Type of chuck | Push button | Identical | Identical |
| **Composition of materials** | | | |
| Materials used in patient-contacting surfaces (external) | Stainless steel | Identical | Stainless steel and titanium |
| Materials used in the water/air tubes (internal) | Stainless steel | German silver and stainless steel | Stainless steel and titanium |
| **Technical Specifications** | | | |
| Chuck design | Push button | Identical | Identical |
| Bur extraction force | 25N | Up to 24 N | 30N |
| Maximum air/water pressure | 36psi to 43psi<br>(40psi recommended) | 30-61 psi<br>(41psi recommended) | Identical |
| Speed in rpms | 330,000-390,000rpm | 340,000-400,000 rpm | 320,000-400,000rpm |
| Compliance standards for shanks | ISO 1797-1 | Identical | Identical |
| Compliance standards for hose connections | ISO 9168 | Identical | Identical |
| **Lubricant** | | | |
| Legally-marketed lubricant (identify 510(k)) | Pana-Spray made by NSK (K052700) | KaVo QUATTROcare (K071288) | Identical |

**Non-clinical Testing Summary** **807.92(b) (1)**

The *Dental High-speed Handpiece Halley Series* was developed taking into consideration all applicable technical standards, internal specifications and FDA guidance documents. The *Dental High-speed Handpiece Halley Series* 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 | 2012 |
| • ISO 1797-1, Dentistry — Shanks for rotary instruments — Part 1: Shanks made of metals | 2011 |
| • 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 | 2009 |
| • 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 | 2004 |
| • 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 |
| • EN 60601-1 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance | IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1: 2012; EN 60601-1: 2006 + A1: 2013 + AC: 2014 |
| • EN 60601-1-2 Medical electrical equipment — Part 1-2: General Requirements for basic safety and essential performance, Collateral standard: Electromagnetic compatibility | IEC 60601-1-2: 2014; EN 60601-1-2:2015 |
| • EN 62471 Photobiological safety of lamps and lamp systems | IEC 62471: 2006; EN 62471: 2008 |

**Clinical Testing Summary** **807.92(b)(2)**

Clinical testing has not been performed.

**Guidance documents used:**

1. Format for Traditional and Abbreviated 510(k)s
2. Bundling Multiple Devices or Multiple Indications in a Single Submission
3. Dental Handpieces - Premarket Notification [510(k)] Submissions
4. The New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications.
5. How to Study and Market Your Device
6. 510(k) Format Tips
7. Content of a 510(k)
8. eCopy Program for Medical Device
9. eSubmitter Quick Guide
10. Indications for Use Statement
11. Labeling Regulatory Requirements for Medical Devices
12. Premarket Notification Truthful And Accurate Statement
13. Refuse to Accept Policy
14. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
15. The 510(k) Program-Evaluating Substantial Equivalence

**Conclusion** **807.92(b)(3)**

Based upon the comparison of technological characteristics, demonstrated through bench testing and intended use, the *Dental High-speed Handpiece Halley Series* is substantially equivalent to the predicate devices.