September 4, 2020

Dentium Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7707 Fannin St. Ste 200, V111
Houston, Texas 77054

Re: K193341
Trade/Device Name: iCTmotor (WL-1)
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: September 3, 2020
Received: September 3, 2020

Dear Dave Kim:

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 Srinivas “Nandu” Nandkumar
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)*
K193341

Device Name
iCTmotor (WL-1)

Indications for Use *(Describe)*

iCTmotor (WL-1) is intended for use in dental surgery and implantology. The main control unit is designed to operate a specific dental micro motor that drives dental handpieces to cut hard and soft tissues in the mouth and screw dental implants. iCTmotor (WL-1) is compatible with a handpiece equipped with connection according to ISO 3964.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K193341

This summary of 510(k) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date 510k summary prepared: September 2, 2020

I. SUBMITTER

Submitter's Name	Dentium Co., Ltd (ICT Branch)
Submitter's Address	76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea (Zip. 16229)
Submitter's Telephone	+82 (70) 7098-4027
Contact person	Sangwoo Lee / RA Manager swlee1@dentium.com
Official Correspondent	Dave Kim (davekim@mtech-inc.net)
Address	Mtech Group 7707 Fannin St. Ste 200-V111 Houston, TX 77054
Telephone	+713-467-2607

II. DEVICE

Trade/proprietary Name	iCTmotor (WL-1)
Common Name	Controller, Foot, Handpieces and Cord
Regulation Name	Dental Handpieces and Accessories
Regulation Number	21 CFR 872.4200
Product Code	EBW
Regulatory Class	Class I

III. PRIMARY PREDICATE DEVICE (K140308)

Primary Manufacturer	Kaltenbach & Voigt GmbH
Device Name	MASTERsurg / EXPERTsurg
Common Name	Controller, Foot, Handpieces and Cord
Regulation Name	Dental Handpieces and Accessories
Regulation Number	21 CFR 872.4200
Product Code	EBW, EGS
Regulatory Class	Class I

IV. DEVICE DESCRIPTION

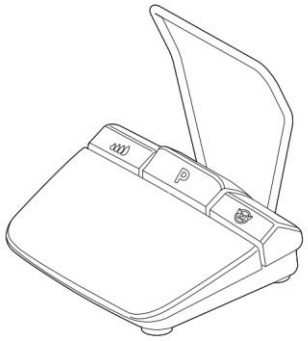
iCTmotor (WL-1) is a software based driving engine that controls the speed of a specific dental micromotor. This device is optimized for dental implant procedures and user programmable parameters operate and control a dental handpiece for dental implant surgery. iCTmotor (WL-1) consists of a main controller unit, a charger, a foot controller, micro motor, cable, a water holder, tube holder, and micro motor holder. The main control unit operates the speed and torque of a dental micromotor that drives dental handpiece to cut tissues in the mouth and to screw dental implants. The main control unit is operated via a wireless foot pedal. The holders are used for placement of a water bag, a micro motor and a handpiece. The power cord delivers electric power to the main control unit.

V. INDICATIONS FOR USE:

iCTmotor (WL-1) is intended for use in dental surgery and implantology. The main control unit is designed to operate a specific dental micro motor that drives dental handpieces to cut hard and soft tissues and screw dental implants. iCTmotor (WL-1) is compatible with a handpiece equipped with connection according to ISO 3964.

VI. PREDICATE COMPARISON

Device name	iCTmotor (WL-1)	EXPERTsurg + INTRA LUXS600 LED	Remarks
510K Number	K193341	K140308	
Main body image			

Foot switch image			Wireless type (same)
Micromotor			Similar
Indication for use	iCTmotor (WL-1) is intended for use in dental surgery and implantology. The main control unit is designed to operate a specific dental micro motor that drives dental handpieces to cut hard and soft tissues in the mouth and screw dental implants. iCTmotor (WL-1) is compatible with a handpiece equipped with connection according to ISO 3964.	Unit: This KaVo product is intended for surgery to expose and dissect oral tissue structures or endodontic treatments (e.g. periodontal gap, gingiva, bone, aw, extractions and implantations). Motor: The medical device is intended to drive / operate a dental handpiece / contra-angle handpiece equipped with a handpiece connection according to ISO 3964. This medical device is an electrical low-voltage motor for dental purposes according to ISO 11498 type 2 and classified as a type B application part.	Similar
Compliance to Standards	Handpiece in compliance with ISO 3964	Handpiece in compliance with ISO	Same
Dimensions	278 x 175 x 134 (mm)	265 x 255 x 100 mm	Similar
Electrical Specification	100 – 240 V	100 – 240 V	Same
Main Weight	3kg	2.0kg	Similar
Foot Weight	0.7kg	1.1kg	Similar

Motor	135g	125g	Similar
Max output power	Max 70W	Max 150W	Different
Motor Type	Surgical Motor (Collector)	Surgical Motor (Collector)	Same
Handpiece Connection	INTRAmatic Coupling System (ISO 3964)	INTRAmatic Coupling System (ISO 3964)	Same
Electrical Specification Motor (Voltage)	36 VDC	22 V AC	Different
Electrical Specification Motor (20:1 Torque)	70Ncm	55 Ncm	Different
Electrical Specification Motor (Torque)	2.3mNm	5.5Ncm	Different
Micro motor LED Input Voltage	DC 3.3V	DC 3.0-3.6V	Similar
Micro motor LED Input Current(Max)	150mA	150mA	Same
Electrical Specification Motor (Rotation)	Clockwise, Counter Clockwise	Clockwise, Counter Clockwise	Same
Electrical Specification Motor (Speed)	400- 40,000rpm	300 - 40,000 rpm	Similar
Pump Delivery rate	40-60ml/min	30-110ml/min	Different
Handpiece rotational speed (20:1 ratio)	20 ~ 2,000 rpm	15 ~ 2,000 rpm	Similar
Wireless foot Emitted power	Max 8.6dBm(e.i.r.p.)	Max 3dBm(e.i.r.p.)	Different
Wireless foot Frequency bend	2.405~2.480GHZ	2.4GHZ	Similar
Length of motor cable	2m	2m	Same
Operating mode	3min ON/10min OFF	30sec. of operation/9min.pause	Different

Handpiece gearing ratio	20:1	20:1	Same
Sterilization	Sterilizable	Sterilizable	Same
Storage Ambient temperature	0℃-+60℃	-20℃-+50℃	Different
Operating Ambient temperature	10℃-+35℃	10℃-+35℃	Same
Storage Relative humidity	Max 90%	5%-95%	Similar
Operating Relative humidity	Max 80%	15%-80%	Similar
Atmospheric pressure Range	700hPa-1,060hpa	700hPa-1,060hpa	Same
Foot switch control	- Speed key - Program key - Motor	- Direction of motor rotation key - Speed key - Program key - Pump key	Similar
Electrical Specification Motor (Speed)	Up to 40,000rpm	Up to 40,000 rpm	Same
Handpiece rotational speed	20 ~ 2,000 rpm	15 ~ 2,000 rpm	Similar
Handpiece gearing	20:1	20:1	Same
Sterilization	Sterilizable	Sterilizable	Same

The proposed iCTmotor (WL-1) is similar in the indications for use, overall design and function to the EXPERTsurg + INTRA LUXS600 LED (K140308). Both the proposed subject device and the primary predicate device consist of a control unit with a micromotor, connecting cable and a wireless foot pedal.

The subject device does not include a straight or contra angle handpiece. An irrigation tube is not included neither.

ICTmotor(WL-1) motor is compatible with any contra-angle handpiece in compliance with EN ISO 3964:2016 and ICTmotor (WL-1) motor is also compatible with irrigation tubes in compliance with EN ISO 7405

The differences do not render the device NSE because the performance tests demonstrate that the differences in technological characteristics do not raise new safety concerns.

VII. SUMMARY OF NON-CLINICAL TESTS

iCTmotor (WL-1) complies with voluntary standards for electrical safety, EMC testing, and use in the dental clinic. The following data were provided to support the substantial equivalence determination:

Electrical Safety:
Testing was conducted in accordance with IEC 60601-1:2012 Medical electrical equipment, Part 1: General requirements for basic safety and essential performance

Electromagnetic Compatibility:
Testing was conducted in accordance with IEC 60601-1-2:2015 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

Software:
Software verification and validation testing as recommended in FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." (May 11, 2005)

Reprocessing:
Cleaning and sterilization validation test report subject to "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" (March 17, 2015) are provided.

Biocompatibility:
The subject device is not in direct contact with a patient's skin. The user is instructed to wear gloves while operating the iCTmotor (WL-1). Therefore, biocompatibility test is not considered.

The manufacturer also provided a material/chemical composition and manufacturing based rationale as to how your final finished device is substantially equivalent to the identified primary predicate device:

"The [Stainless Steel: SUS 304] of iCTmotor (K193341) in its final finished form is identical to the [Stainless Steel: SUS 304] of other micro motor manufactured by Maxon motor ag and marketed in the US in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents)."

" iCTmotor micro motor in its final finished form is identical to other micro motor manufactured by Maxon motor ag and marketed in the US as private labels in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents)."

Performance testing was conducted cording to ISO 14457:2012 to show that the device meets its design requirements and performs as intended. The specifications were met for:

- Rotating speed of micromotor
- Torque of micromotor
- Stop of micromotor
- Rotating direction of micro motor
- Irrigation amount

VIII. SUMMARY OF CLINICAL TESTS

Clinical testing was not required to demonstrate the substantial equivalence of iCTmotor (WL-1) to its predicate device.

IX. CONCLUSIONS

Based on the information above, iCTmotor (WL-1) is substantially equivalent to the predicate device. Based on the performance testing results including the nonclinical tests, the subject device is as safe, as effective, and performs as well as or better than the legally marketed device predicate (21 CFR 807.92(b)(3))