March 11, 2024

Codent Technical Industry Co., Ltd.
Jyun-Ming Shuo
Deputy Manager of Quality Assurance
2F., No.100, Luke 5th Rd., Luzhu Dist.
Kaohsiung City, 821
Taiwan

Re: K231864
Trade/Device Name: Fiber Optic Brushless Electronic Micromotor, model: iM100
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW
Dated: February 19, 2024
Received: February 20, 2024

Dear Jyun-Ming Shuo:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Bobak Shirmohammadi -S

For Michael Adjodha, MChE, RAC, CQIA
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)*

K231864

Device Name
Fiber Optic Brushless Electric Micromotor Set (iM100)

Indications for Use *(Describe)*

The Fiber Optic Brushless Electric Micromotor Set (iM100) is a brushless DC electric micromotor controlled by a control unit. It is intended to be connected with an ISO-type handpiece attachment: straight or contra-angle of equal, gear reducing, or gear increasing speed. It is indicated for use in the field of preventive dentistry, restorative applications including cavity preparation and endodontic therapy, prosthodontics applications such as crown preparations.

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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K231864

510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: June 13, 2023

5.3 Submitter:

Address: 2F., No.100, Luke 5th Rd., Luzhu Dist., Kaohsiung City 821, Taiwan.
Phone: +886-7-6955533
Fax: +886-7-6955683
Contact: I-Ching Fang (service@codent-tech.com)

5.4 Identification of the Device:

Proprietary/Trade name:	Fiber Optic Brushless Electric Micromotor Set (iM100)
Classification Product Code:	EBW
Regulation Number:	872.4200
Regulation Description:	Dental handpiece and accessories
Review Panel:	Dental
Device Class:	I
Basis for the Submission:	New Device

5.5 Identification of the Predicate Device:

Device Name:	Electric Handpiece Motor EM-12 L
Applicant:	W & H DENTALWERK BÜRMOOS GMBH
Classification Product Code:	EBW
Regulation number:	872.4200
Device Class:	I
510(k) Number:	K181858

5.6 Indications for Use of the Device

The Fiber Optic Brushless Electric Micromotor Set (iM100) is a brushless DC electric micromotor controlled by a control unit. It is intended to be connected with an ISO-type

handpiece attachment: straight or contra-angle of equal, gear reducing, or gear increasing speed. It is indicated for use in the field of preventive dentistry, restorative applications including cavity preparation and endodontic therapy, prosthodontics applications such as crown preparations.

5.7 Device Description

The Fiber Optics Brushless Electric Micromotor Set, which model is iM100, is an electric device system comprised of brushless electric motor, control box, motor cord, and AC adapter.

The Fiber Optics Brushless Electric Micromotor Set is designed to accommodate equal speed, gear-reduction speed, or gear-increasing speed handpiece attachment for the purpose of performing dental restoration procedures. Brushless electric motor utilize Permanent Magnet Synchronous Motor (PMSM) to offer stable torque, control box adjust the maximum speed and direction of brushless electric motor and show actual speed rate simultaneously, motor cord connect electric motor, control box and dental unit to offer handpiece water, air coolant and electricity. When equipped with the electric micromotor, the handpiece attachments provide the same effective drive force as would be provided by existing air motors.

With motor control technology allows handpieces regardless of the front-end dental treatment operations or exposure to different functional groups or dental restorative material, and the speed of the drill can be kept within a certain extent but not easily change the load that make brushless electric motor operation is more easily and efficiently, unlike the operation of the air motor handpiece need to keep relied dentist technical experience. The Fiber Optics Brushless Electric Micromotor Set could control the speed range from 2,000 to 40,000 rpm.

5.8 Substantial Equivalence Determination

Equivalence, same and difference between the subject and predicate devices are cited as below.

Item	Subject Device	Predicate Device	Substantial Equivalence Determination
Proprietary Name	Fiber Optic Brushless Electric Micromotor Set (iM100)	Electric Handpiece Motor EM-12 L	
510(k) No.	(to be assigned)	K181858	
Indications for Use	The Fiber Optic Brushless Electric Micromotor Set (iM100) is a brushless	Electric Handpiece Motor EM-12 L is a brushless DC	**Same** Both devices are the

Item	Subject Device	Predicate Device	Substantial Equivalence Determination
Proprietary Name	Fiber Optic Brushless Electric Micromotor Set (iM100)	Electric Handpiece Motor EM-12 L	
510(k) No.	(to be assigned)	K181858	
	DC electric micromotor controlled by a control unit. It is intended to be connected with an ISO-type handpiece attachment: straight or contra-angle of equal, gear reducing, or gear increasing speed. It is indicated for use in the field of preventive dentistry, restorative applications including cavity preparation and endodontic therapy, prosthodontics applications such as crown preparations.	electric micromotor controlled by a control unit. The electrical drive, EM-12 L is indicated for use in the field of preventive dentistry, restorative applications including cavity preparation and endodontic therapy, prosthodontics applications such as crown preparations.	brushless electric micromotor used to drive a dental handpiece.
Type of use	Prescription Use	Prescription Use	**Same**
Components	Brushless electric motor, control box, motor cord, and AC adapter	Electric motor, motor controller, motor tubing	**Equivalent** All components are essential as the motor set.
Device Design			
Photo of the motor			**Equivalent** The difference does not raise new issues of SE.
Air/water ports	Yes	Yes	**Same**
Dimensions of the motor	Length 50 mm Weight 87 g	Length 31.55 mm Weight 57 g	**Equivalent** The difference in device dimensions does not raise new issues of SE.
Dimensions of the controller	D150mm x W125mm x H56mm Weight 500 g	D211mm x W156mm x H92mm Weight 1.06 kg	

Item	Subject Device	Predicate Device	Substantial Equivalence Determination
Proprietary Name	Fiber Optic Brushless Electric Micromotor Set (iM100)	Electric Handpiece Motor EM-12 L	
510(k) No.	(to be assigned)	K181858	
Light on the motor	LED	LED	**Same**
Composition of Materials			
Waterlines and the patient-contacting part (indirect)	Stainless Steel, PU, and PVC in compliance with ISO 10993-1	Materials and surface in compliance with ISO 10993-1	**Equivalent** The material evaluation of both devices demonstrates biocompatibility and does not raise new issues of SE.
Technical Specifications			
Max. torque	3 Ncm	3 Ncm	**Same**
Air pressure	1.5NL/min at 2.5bar	cooling air >8Nl/min at 2.5bar	**Equivalent** The subject device has been tested and met its pre-defined criteria, so that the difference does not raise new issues of SE.
Water pressure	50ml/min at 2.5bar	spray water >200ml/min at 2 bar	
Speed range	2,000 - 40,000 rpm	100 - 40,000 rpm	
Power supply	AC 100-240V	100 – 240 V AC	**Same**

5.9 Similarity and Difference

The Fiber Optic Brushless Electric Micromotor Set (iM100) has been compared with "Electric Handpiece Motor EM-12 L". The subject device has same intended use, similar principle of operation and technological characteristics as the predicate device.

Although there are some different specifications between two devices, the safety and performance test of subject device has been completed and the results complied with the test requests. Main compliance standards are ISO 14457, ISO 10993-1, IEC 60601-1, IEC 80601-2-60, ISO 3964, and ISO 9168, supporting the finding of substantial equivalence with predicate device.

Therefore, the differences between the subject device and the predicate device do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device in intended use, design, and performance claims.

5.10 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device as below.

- Shelf Life and Warranty Life
- Biocompatibility
- Software Validation
- Electromagnetic compatibility and electrical safety
- Performance and usability

All the test results demonstrate Fiber Optics Brushless Electric Micromotor Set (iM100) meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

5.11 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.12 Conclusion

After comparing the devices and analyzing non-clinical safety & performance testing data, it can be concluded that the Fiber Optic Brushless Electric Micromotor Set (iM100) is substantially equivalent to the predicate device.