September 27, 2022

Foshan COXO Medical Instrument Co., Ltd.
℅ Ray Wang
Gerneral Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District
Beijing, Beijing 102401
CHINA

Re: K220831
Trade/Device Name: Dental Implantation Systems, Dental Electrical Motors
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece And Accessories
Regulatory Class: Class I, reserved
Product Code: EBW, KMW, EGS
Dated: July 15, 2022
Received: July 18, 2022

Dear Ray Wang:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220831

Device Name
Dental Implantation Systems/Dental Electrical Motors

Indications for Use *(Describe)*

C-Sailor Pro:

This device is intended for use in dental oral surgery and dental implant.The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard tissues in the mouth. It must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

C-PUMA MASTER:

The Dental Electrical Motor is intended for use in dental oral surgery and dental implant. The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard tissues in the mouth.

This device is designed for use by a trained professional in the filed 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.

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

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The assigned 510(k) Number: K220831

510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

1. Date of Preparation: 07/15/2022

2. Sponsor Identification

Foshan COXO Medical Instrument Co., Ltd.

BLDG 4, District A, Guangdong New Light Source Industrial Base, South of Luocun Avenue, Nanhai District, Foshan, 528226, Guangdong, China

Contact Person: Zheng Yongjian
Position: Legal Representative
Tel: 13702544788
Fax: 0757-81800058
Email:13702544788@163.com

3. Designated Submission Correspondent

Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd., FangShan District, Beijing, China,102401

Contact Person: Ray Wang
Position: General Manager
Tel: +86-18910677558
Fax: +86-10-56335780
Email: information@believe-med.com

4. Identification of Proposed Device

Trade Name: Dental Implantation Systems, Dental Electrical Motors
Common Name: Controller, Foot, Handpiece And Cord; Handpiece, Rotary Bone Cutting; Handpiece, Contra- And Right-Angle Attachment, Dental

Regulatory Information
Classification Name: Dental
Classification: 2
Product Code: EBW, KMW, EGS
Regulation Number: 872.4120
Review Panel: Dental

Device Description:
The proposed device is used to provide the driving force of dental mobile phone for dental surgery. The functions corresponding to the dental operation steps are preset through the host or foot switch, and the electric energy and signal are transmitted to the motor through the motor cable. The motor drives the mobile phone, and the mobile phone drives the dental operation instruments to perform the operation.
The Dental Implantation Systems(C-Sailor Pro) consists of the Host, the Foot Control, AC Electrical Cord, Motor (With Cable), Handpiece Stand, Tube Holder, Spare Fuse, Handle (Foot control), and Stand for use with specific Motors. The Dental Electrical Motors(C-PUMA MASTER) consists of the Control Unit, Electrical Motor, Adaptor, Power Cord, Handpiece Stand and Motor Shaft Plug for use with specific Motors.
The two models of proposed device have the same operating principle shown as following:
The functions corresponding to the dental operation steps are preset by the mainframe or pedal switch, and the electric energy and signals are transmitted to the motor through the motor cable, the motor drives the motor handle, and the motor handle drives the dental surgical instruments to carry out the operation.

Intended Use:
C-Sailor Pro:
This device is intended for use in dental oral surgery and dental implant.The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard tissues in the mouth.
It must only be used in hospital environments, clinics or dental offices by qualified dental personnel.
C-PUMA MASTER:
The Dental Electrical Motor is intended for use in dental oral surgery and dental implant. The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard tissues in the mouth.
This device is designed for use by a trained professional in the filed of general dentistry.

5. Identification of Predicate Device(s)

Predicate Device
510(k) Number: K173905
Product Name: Surgic Pro, Surgic Pro+
Manufacturer: NAKANISHI INC.

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- EC 60601-1-2:2014, Medical Electrical Equipment-Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility-Requirements And Tests;
- IEC 80601-2-60:2019 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment;
- ISO 14457 Second edition 2017-10 Dentistry - Handpieces and motors
- ISO 10993-5 Biological evaluation of medical device -Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10 Biological evaluation of medical device - Part 10: Tests for irritation and skin sensitization.
- ISO 14971 Medical devices - Application of risk management to medical devices
- Bench Testing for the performance of Dimensions.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

ITEM	Proposed Device	Predicate Device K173905	Remark
Intended Use	C-Sailor Pro: This device is intended for use in dental oral surgery and dental implant.The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard tissues in the mouth. It must only be used in hospital environments, clinics or dental offices by qualified dental personnel. C-PUMA MASTER:	Surgic Pro+ / Surgic Pro The Surgic Pro+ / Surgic Pro is intended for use in dental oral surgery and dental implant. The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard tissues in the mouth. The SG20 and X-SG20L This medical device is for oral surgery and dental implant operation. This device	SAME

	The Dental Electrical Motor is intended for use in dental oral surgery and dental implant. The main unit is designed to be used with a specific dental micromotor that drives dental handpieces fitted with appropriate tools to cut hard tissues in the mouth. This device is designed for use by a trained professional in the filed of general dentistry.	is driven by an electronic micromotor for oral surgery and dental implant. The device is intended to transmit the rotation of the power source at different gear ratios, thereby moving instruments such as surgical burs or surgical drills to cut the maxilla / mandible during oral surgery and dental implant.	
Indications for Use	Prescription Use, dental oral surgery, dental implant	Prescription Use, dental oral surgery, dental implant	SAME
Package Contents	Host Foot Control (With Cable) AC Electrical Cord Motor (With Cable) Stand Handpiece Stand Tube Holder Spare Fuse Handle(Foot control) Irrigation tubing set	Control Unit Micromotor (Optic or Non-Optic) Foot Controller Handpiece (Optic or Non-Optic) Irrigation tube (5 pcs) Operation Manua	Analysis 1
Memory	8 Pre-set implant systems	8 Pre-set implant systems 8 user defined of 8 steps each	SAME
Micromotor Torque	C-Sailor Pro: 5 - 80Ncm C-PUMA MASTER: 0.6-5.1Ncm	5 - 80Ncm	SAME
Maxima speed	C-Sailor Pro: 300r/min～40000r/min C-PUMA MASTER: 2000～40000rpm	200-40,000 min^{-1}	Analysis 2
Speed ratio option	C-Sailor Pro: 64:1, 20:1, 16:1, 10:1, 4:1, 1:1, 1:5 C-PUMA MASTER: 16:1, 1:1, 1:5	Not available	Analysis 3
Discharge	C-Sailor Pro: ≥50ml/min C-PUMA MASTER: ≥50ml/min(200kPa)	Not available	
Spray gas flow rate	C-Sailor Pro: / C-PUMA MASTER: ≥1.5L/min(200kPa)	Not available	
Cooling gas flow	C-Sailor Pro: / C-PUMA MASTER: ＜40L/min(250kPa-500kPa)	Not available	
Adapter	C-Sailor Pro: / C-PUMA MASTER: Input：100V-240V～ 50/60Hz 2.5A Output：29.5V⎓4.8A	Not available	
Classification of degree of protection	C-Sailor Pro: Type B C-PUMA MASTER: Type B	Not available	

against electric shock			
Classification of types of protection against electric shock	C-Sailor Pro: Class II C-PUMA MASTER: Class II	Not available	
light source	C-Sailor Pro: LED 3.3V C-PUMA MASTER: LED 3.3V	Not available	
Handpiece Coupling	ISO 3964	ISO 3964	SAME
Handpiece Chuck Mechanism	Push-button	Push-button	SAME
Bur	Type and dimension of shank and minimum fitting length of shank in accordance with ISO 1797	Ø 2.35mm/ Type 1 (ISO 1797)	SAME
Foot Control Degree of Protection	IPX7	IPX8	Analysis 4

Analysis 1:
The proposed device is different with the predicate device in package contents, which may raise the risk about biocompatibility, for this risk we have conducted the testing according to the ISO 10993-1, cytotoxicity, irritation and sensitization. The test results shown that no biocompatibility risk would be raised.
So, we consider that the proposed device has same biocompatibility performance with the predicate device.

Analysis 2:
The proposed device is different with the predicate device in Micromotor Torque, but the intended use is the same, for this risk we have conducted the ISO 14457 Test Report, EMC Test Report and IEC 80601-2-60 Test Report, the test results shown the difference does not raise any risk.

Analysis 3:
We are not sure whether the proposed device and the predicate device are exactly the same in Speed ratio option, Discharge, Spray gas flow rate, Cooling gas flow, Adapter, Classification of degree of protection against electric shock, Classification of types of protection against electric shock and light source, because we can't get the technical specifications for predicate device, but the intended use is the same, for this risk we have conducted the ISO 14457 Test, EMC Test and IEC 80601-2-60 Test, the test results shown the difference does not raise any risk.

Analysis 4:
The proposed device is different with the predicate device in foot control degree of protection, which may raise the risk about safety, for this risk we have conducted the testing according to the IEC 80601-2-60. The test results shown that the proposed device conforms to IEC 80601-2-60.
So, both the proposed device and the predicate device meet the safety requirements of IEC

80601-2-60.

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.