DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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DMETEC Co., Ltd.
% Yang Dong
CEO
Onbix Corporation
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Gangnam-gu, Seoul 06253 KR

December 27, 2017

Re: K170104
Trade/Device Name: Compact S
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC
Dated: November 22, 2017
Received: November 30, 2017

Dear Yang Dong:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170104

Device Name
COMPACT S, COMPACT S(LED)

Indications for Use *(Describe)*
- removing supra and subgingival calculus and stains
- periodontal pocket lavage with simultaneous ultrasonic tip movement
- scaling and root planning
- releasing crowns, bridges, inlays and posts as well as condensing gutta percha
- plugging for amalgam condensation
- amalgam burnishing
- preparing, cleanig, and irrigating root canals
- preparing approximal cavites
- cementing inlays and onlays
- retrograde preparation of root canals

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

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Date Summary Prepared: Dec 27, 2017

Device Information:

Trade Name(s):	**COMPACT S, COMPACT S(LED)**
Classification Name:	SCALER, ULTRASONIC
Panel:	dental
Product Code & Regulation:	ELC / 872.4850

Predicate Device Information:
K060171 / CLEANSE S+ ULTRASONIC SCALER / DMETEC Co., Ltd.

Device Description:
The purpose of the device is to remove plaque from the surface of the tooth through using ultrasonic vibration generated by the electricity(24 V~) and water supply received in a dental chair and other dental devices.
The product is provided in the form of parts that can be installed and used inside a dental chair and other dental devices. The control of the water supply is made from the dental chair and other dental devices.

Indications for Use:
- removing supra and subgingival calculus and stains
- periodontal pocket lavage with simultaneous ultrasonic tip movement
- scaling and root planning
- releasing crowns, bridges, inlays and posts as well as condensing gutta percha
- plugging for amalgam condensation
- amalgam burnishing
- preparing, cleanig, and irrigating root canals
- preparing approximal cavites
- cementing inlays and onlays
- retrograde preparation of root canals

Summary of the technological characteristics compared to the predicate device

The proposed Compact S is virtually identical to the previously approved CLEANSE S + (ULTRASONIC SCALER, K060171).

Compact S is a model of drive module with the exterior case, power control keypad, and control device removed from the body of the previously approved product (CLEANSE S +), and can be installed to the dental chair.

The difference between the input powers of the two devices is that the previously approved product uses an adapter, and the proposed product is in a different form, powered by the dental chair.

The output current is also lowered from 40 VA to 24 VA due to structural changes due to the removal of the control keypad. However, the output of the handpiece is similar for both devices.

The difference between the two devices does not affect their safety or performance.

The device was conducted in compliance with the following Standard

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) : Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007 (Third Edition) : Medical Electrical Equipment PART 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility
- IEC 80601-2-60: 2012 (First Edition) : Medical electrical equipment: Part 2: Particular requirements for basic safety and essential performance of dental equipment

Comparison table is as follows

	DMETEC (COMPACT S)	DMETEC (Cleanse S+)
510(k) reference	Proposed	K060171
Indication for use	- removing supra and subgingival calculus and stains - periodontal pocket lavage with simultaneous ultrasonic tip movement - scaling and root planning - releasing crowns, bridges, inlays and posts as well as condensing gutta percha - plugging for amalgam condensation - amalgam burnishing - preparing, cleanig, and irrigating root canals - preparing approximal cavites - cementing inlays and onlays - retrograde preparation of root canals	- removing supra and subgingival calculus and stains - periodontal pocket lavage with simultaneous ultrasonic tip movement - scaling and root planning - releasing crowns, bridges, inlays and posts as well as condensing gutta percha - plugging for amalgam condensation - amalgam burnishing - preparing, cleanig, and irrigating root canals - preparing approximal cavites - cementing inlays and onlays - retrograde preparation of root canals
Supply voltage	AC/DC 24 V, 50/60 Hz	Transformer input : 100-240 V AC , 50/60 Hz Transformer output : DC 24V
Water supply pressure	1 to 5 bar (15 to 72 psi)	1 to 5 bar (15 to 72 psi)
Maximum output power with load	24VA	40VA

Frequency range available	24-32 kHz	24-32 kHz
mode	Continuous	Continuous
Connection to second scaler unit	Not allowed	Not allowed
Main component	• Unit Body : 1ea • Hand-piece : 1ea (Normal type or LED type) • Tip(Basic) : 3ea • Tip(option) : 2ea	• Unit Body : 1ea • Hand-piece : 1ea(Normal type) • Tips(Basic) : 3ea • Tip(option) : 2ea

※Compact S is a model of drive module with the exterior case, power control keypad, and control device removed from the body of the previously approved product (CLEANSE S +), and can be installed to the dental chair.

※The COMPACT S and Cleanse S + use the same handpiece made from the same material.

COMPACT S&COMPACT S LED		
1	Vibrator	Titanium+SUS
2	Outsider cap	PPSU/25mm 8Ø-17Ø
	Outsider cap ***(LED Type)***	17.6Φ*23.7mm
3	H.P BODY	PPSU/68mm 14Ø-17Ø
	H.P BODY ***(LED Type)***	PPSU/70mm 18.5Φ-17.5Φ
4	HP Socket (Upper)	PPSU/12.5mm 15Ø
5	HP socket (down)	PPSU/15mm 11.5Ø
6	Handpiece C	PPSU/19mm 8
7	O-ring 3Φ 1.8T	Rubber/006
8	Vibrator O-ring down	10Ø*1mm
9	Handpiece socket O-ring Upper	Rubber/S11
10	Water pin O-ring1Φ1T	Rubber/P2
11	Terminal pin female	4*21.8mm
12	Water pin	inside1Ø 4*21mm
13	LED Module ***(LED Type)***	Ø15.2*18.5mm

Cleanse S+		
1	Vibrator	Titanium+SUS
2	Outsider cap	PPSU/25mm 8Ø-17Ø
	-	-
3	H.P BODY	PPSU/68mm 14Ø-17Ø
	-	-
4	HP Socket (Upper)	PPSU/12.5mm 15Ø
5	HP socket (down)	PPSU/15mm 11.5Ø
6	Handpiece C	PPSU/19mm 8
7	O-ring 3Φ 1.8T	Rubber/006
8	Vibrator O-ring down	10Ø*1mm
9	Handpiece socket O-ring Upper	Rubber/S11
10	Water pin O-ring1Φ1T	Rubber/P2
11	Terminal pin female	4*21.8mm
12	Water pin	inside1Ø 4*21mm
-	-	-

※The difference between the two types of handpieces is the presence or absence of LEDs illuminating the mouth.

Tip material (contact with patient)	• Stainless steel(SUS420J2)	• Stainless steel(SUS420J2)
	※The COMPACT S and Cleanse S + use the same shaped tip for the same material.	

Summary of Non-Clinical performance testing as basis for substantial equivalence
Non-clinical performance testing demonstrates that all design inputs for the Compact S is satisfied by the design outputs. Testing of the device, when integrated with a dental chair and handpiece was performed. Results of the integration testing showed that the device met electrical safety (IEC 60601-1) and electromagnetic compatibility (IEC 60601-1-2) requirements. Additional integration testing included basic and essential performance as well as validation of the software in its actual use. Results from the functional and performance testing showed that the device met the predetermined acceptance criteria. The similarities in intended use, operational characteristics, and functional technological characteristics between the proposed Compact S and the parent Clenase S+ lead to a conclusion of substantial equivalence between the proposed and predicate device.
The results of this testing confirm that the Compact S is as safe and effective as the predicate device for the intended use.

Summary of clinical test as basis for substantial equivalence.
No clinical testing was conducted to support this submission.

Summary of non-clinical performance testing
all performance bench tests, sterilization and cleaning validations, biocompatibility, electrical and EMC and software.

The device was conducted in compliance with the following Standard
- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) : Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2007 (Third Edition) : Medical Electrical Equipment PART 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility
- IEC 80601-2-60: 2012 (First Edition) : Medical electrical equipment: Part 2: Particular requirements for basic safety and essential performance of dental equipment
- ISO 17665-1/2 Sterilization of health care products
- IEC 62304: 2006 : Medical device software Software life-cycle processes
- ISO 10993-1: 2009 : Biological evaluation of medical devices biocompatibility

Conclusion drawn from non-clinical and clinical tests
The similarities in intended use, operational characteristics, and functional technological characteristics between the proposed COMPACT S and the Cleanse S+ lead to a conclusion of substantial equivalence between the proposed and predicate device