February 13, 2025

Denjoy Dental Co., Ltd.
Chengfa Huang
Quality Manager
F4, Building A4, Lugu Medical Device Park, No.229
Guyuan Road
Changsha, Hunan 410205
CHINA

Re: K242317
Trade/Device Name: Integrated Endo System (Meet Endo-II)
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC, EKX, EKR, LQY
Dated: January 14, 2025
Received: January 14, 2025

Dear Chengfa Huang:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

MICHAEL E. ADJODHA -S

Michael Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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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.

Submission Number *(if known)*

K242317

Device Name

Integrated Endo System (Meet Endo-II)

Indications for Use *(Describe)*

The Integrated Endo System is dental device which combine in a single main control unit an endo motor to clean the root canal, a dental obturator to fill and pressurize, an electronic apex locator to assist the operator to locate the file tip in the root canal and an ultrasonic-handpiece for root-canal cleaning and preparation.
The Integrated Endo System is intended solely for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.

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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Section 5 - 510(k) Summary

K242317
Date of Summary Preparation: 08/05/2024
Date of Summary Revision: 01/14/2025

1. Submitter's Identifications

Submitter's Name: DENJOY DENTAL CO., LTD
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2. Correspondent’s Identifications

Correspondent’s Name: Guangzhou Junyi Information Technology Co., Ltd.
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3. Device Identification

Trade Name: Integrated Endo System
Model: Meet Endo-II
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Common Name: Scaler, Ultrasonic
Regulatory Class: Class II
Product Code: ELC, Ultrasonic Scaler
EKX, direct drive, AC-powered handpiece
EKR, edodontic plugger, root canal
LQY, root apex locator (unclassified)
Review Panel: Dental

4. Predicate Devices

K202906 EndoPilot^2

5. Device Description

The Integrated Endo System Meet Endo-II is composed of Main Unit, Adapter, MeetMotor, MeetFill, MeetPex, MeetActivator. It is standalone AC-powered dental control units with a touch display screen to which multiple hand-held dental handpieces for root canal therapy procedure (MeetMotor is for root canal preparation, MeetFill is for root canal backfilling, MeetPex is for working length measurement of root canal, MeetActivator is for root canal irrigation).
These multifunctional devices are intended for use by professionals in the dental clinic use environment. Based on the modular concept of the Integrated Endo System different handpieces can be combined with the control unit. The key hand-held components like handpieces or endodontic tools of the Integrated Endo System are medical devices commercially available by themselves and have separate FDA registration or clearance for marketing in the US.

6. Indications for Use

The Integrated Endo System is dental device which combine in a single main control unit an endo motor to clean the root canal, a dental obturator to fill and pressurize, an electronic apex locator to assist the operator to locate the file tip in the root canal and an ultrasonic-handpiece for root-canal cleaning and preparation.
The Integrated Endo System is intended solely for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.

7. Substantial Equivalence Discussion

Table 1 Comparison of Characteristic between Subject Device and Predicate Devices

Attribute	Subject Device	Predicate Device	Device Comparison
510k number	K242317	K202906	------
Proprietary name	Integrated Endo System	EndoPilot^2	------
Model	Meet Endo-II	/	**------**
Manufacturer	DENJOY DENTAL CO., LTD	Schlumbohm GmbH & Co. KG	------
Regulation number **Regulation Name** **Product Codes**	872.4200 Dental Handpiece and Accessories EKX, direct drive, AC-powered handpiece 872.4565 Dental hand instrument EKR, endodontic plugger, root canal LQY, root apex locator (unclassified) 872.4850 Ultrasonic scaler ELC Ultrasonic scaler		Same
Regulatory Class	Class II	Class II	Same
Indications for use	The Integrated Endo System is dental device which combine in a single main control unit an endo motor to clean the root canal, a dental obturator to fill and pressurize, an electronic apex locator to assist the operator to locate the file tip in the root canal and an ultrasonic-handpiece for root-canal cleaning and preparation. The Integrated Endo System is intended solely for use by trained dental professionals in professional health care facilities on	The EndoPilot^2 systems are dental devices which combine in a single control unit an endo motor to clean the root canal, a dental obturator to fill and pressurize, an electronic apex locator to assist the operator to locate the file tip in the root canal and an ultrasonic-handpiece for rootcanal cleaning and preparation. The EndoPilot^2 is intended solely for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.	Same

	patients that need root-canal-treatment.		
Professional Use	Dental professionals		Same
Location of Use	Dental practice		Same
Mode of Action	Endo-Motor: ablates the tooth to clean the root canal (rotating endo-files) Obturation Unit: to fill and pressurize various shaped packing elements (Warming up by a resistance-wire) Apex locator: to ensure the location of the front tip in root canal through changes of electric resistance value into one unit (Electrical impedance) Display: displayed through a single touch screen		Same
AC/DC Power Supply	AC: 100-240V, 50/60Hz DC: 24V, 3A	AC: 100-240 V, 50/60 Hz DC: 12 V, 1.5 A	Similar DC difference results out of the higher power consumption for Integrated Endo System power adapters
Battery Operated	Yes, Li-Ion battery, 14.4V, 4800mAh, 69.12Wh	Yes, Li-Ion battery, 7.2V, power output 48Wh	Different Battery tested for IEC 62133-2
Components for system	1) Main unit with display panel (touch screen), 5 connecting sockets, power supply and wireless charging 2) MeetPex (Probe cable (single), Probe cable (double), Extension cable for hook, File holder, Mouth hook, Probe needle, Locator) 3) MeetMotor 4) MeetFill (D274830) 5) MeetActivator	1) Control unit with display panel (touch screen), 5 connecting sockets, a microSD slot, power supply and wireless footswitch 2) Apex cable set (Lip-clip, Cap for Lip-clip, Cable for file clamp, File clamp, Retainer for apex cable, measuring cable) 3) Contra-angle for apex measurement 4) Endodontic Motor with apex measuring contact 5) DownPack (D-Pack) handpiece with LED	Similar The small differences in design do not raise new questions of substantial equivalence

		indicator 6) BackFill handpiece (K042828) 7) Ultrasonic handpiece, Ultrasonic Module (K050895)	
Processing (reuse of components sterilized by user)	To be reprocessed in the dental practice before re-use.		Similar Manuals include reprocessing instruction based on ISO 17664-1/17665-1
Electrical Safety	IEC 60601-1 IEC 80601-2-60	IEC 60601-1 IEC 80601-2-60	Same
Protection type and level against electric shock	Class I equipment, Type BF applied part	Class II equipment, Type BF applied part	Similar Equivalent technology is used
Electromagnetic Compatibility	IEC 60601-1-2 IEC TR 60601-4-2	IEC 60601-1-2 IEC 61000-3 series IEC 61000-4 series (2,3,4,5,6,8,11)	Same IEC 60601-1-2:2014+A1:2020 and IEC TR 60601-4-2:2016 tests of subject device have included the relevant standards test of predicate device.
Technological comparison of System Component Functions			
Main Unit and display, Apex cable set and foot switch			
Device Display Function	LCD Touchscreen for display of working components	LCD Touchscreen for display of working components	Same
Functional Specification	All main function can be selected directly at the start screen The device switches off after a longer period of non-operation		Same
Accessory Foot Switch Function	None	Single wireless footswitch or optional Twin wireless footswitch	Different This difference does not raise new questions
Wireless connection/Bluetooth	2400-2483.5 MHz, TX Power: ⩽ 20 dBm	2.402-2.480 GHz, TX Power: +7 dBm	Similar The small differences in design do not raise new questions of substantial

			equivalence

Attribute	Subject Device	Predicate Device	Device Comparison
510k number	------	K202906	------
Proprietary name	Integrated Endo System	EndoPilot^2	------
Model	Meet Endo-II	/	**------**
Manufacturer	DENJOY DENTAL CO., LTD	Schlumbohm GmbH & Co. KG	------
Apex locator (Apex cable set)			
Function	Apex location of the front tip (of the endo-file) in the root canal through changes of electric resistance value		Same
Apex locator	MeetPex	Electronic apex locator (Schlumbohm)	Same
Apex cable set components (material)	Probe cable (single & double) (TPR Plastic Class VI), Extension cable for hook (TPR Plastic Class VI), File holder (Rubber), Mouth hook (Stainless steel), Probe needle (Rubber, stainless steel)	Lip clip (Stainless-Steel) cap for lip-clip plug socket (POM-C) 58 mm 2mm File clamp (USP Plastic Class VI), cable for file clamp (TPR Plastic Class VI) Length 65 mm, Diameter 12 mm Measuring cable (PVC), 1.5 m twin cable Retainer for apex cable (Stainless steel) (rest at the device)	Similar Small difference in design does not impact the device
Functional Specification	Accuracy of Apex Locating point < ±0.5 mm	Accuracy of Apex Locating point < ±0.5 mm	Same
Contra angle			
Function	holds the "drill bit" and/or endodontic files used in endodontic procedures e.g. root canal preparation		Same

Functional Specification	26*28*140mm, Weight 128g Torque range: Max. 5 Ncm +/- 10% (Gear ratio: 6:1)	Φ20 x 94 mm, Weight 52.0g Torque range: Max. 5 Ncm +/- 10% (Gear ratio: 1:1)	Similar Small difference in design does not impact the device
Mode of Operation	Forward and reverse		Same
Material	Aluminum	Hard chrome plated brass	Different The difference in design does not impact the device
Accessories (Endo Files)	Database with preset values for parameters for selected Endodontic Files from File-manufacturers	Database with preset values for parameters for selected Endodontic Files from File-manufacturers	Same

Attribute	Subject Device	Predicate Device	Device Comparison
510k number	------	K202906	------
Proprietary name	Integrated Endo System	EndoPilot^2	------
Model	Meet Endo-II	/	**------**
Manufacturer	DENJOY DENTAL CO., LTD	Schlumbohm GmbH & Co. KG	------
Endodontic motor			
Function	Micro motor (dental handpiece) provides power for contra angle to be used together in standard endodontic procedures (root canal preparation)		Same
Functional Specification	26*28*140mm Weight 128g (including wire) File Rotation Speed: 100-1500 rpm Torque limit value: 0.4-5.0 Ncm Gear ratio: 6:1 (contra angle) Auto-reverse mode Auto-stop mode Speed Control Torque Control	Φ21 x L 107 mm Weight 132 g (including wire) File Rotation Speed: 200-1000 rpm Torque limit value: 0.2-5.0 Ncm Gear ratio 1: 1 (contra angle) Auto-reverse mode Auto-stop mode Speed Control Torque control	Similar Both rotation speed are low speed ranges for dental motors
Material	Stainless steel	Stainless steel	Same

Obturation Unit Back (DownPack, BackFill handpiece, Gutta Percha)			
Function	fill and pressurize various shaped packing elements (Gutta percha)		Same
Reference to FDA-cleared component	D274830, MeetFill, by DENJOY DENTAL CO., LTD	K042828, Obtura Heated Gutta Percha System, by YOUNG OS LLC	----
Functional Specification	MeetFill (D274830), 29*30*178mm, Weight 150g Working temperature:100-200℃ ±10%, adjustable Injection needle Diameter: 23 gauge, 24 gauge, 25 gauge Working length: 25.5 mm	Manual DownPack handpiece Φ14 x L 130.5 mm, weight 72 g Working temperature up to 300°C adjustable Pack tip/heating tip (E & Q Master; elements free), FDA-registered by MetaBiomed Manual BackFill handpiece (K042828) ΦHeating Unit 12.5 mm x 150.5 mm x 21.5 mm, Weight: 63g Working temperature up to 200°C, adjustable BackFill Needles Diameter: 20 gauge, 23 gauge, 25 gauge working length 25.5 mm	Similar The difference in use is verified in the bench test

Attribute	Subject Device	Predicate Device	Device Comparison
510k number	------	K202906	------
Proprietary name	Integrated Endo System	EndoPilot^2	------
Model	Meet Endo-II	/	**------**
Manufacturer	DENJOY DENTAL	Schlumbohm GmbH	------

	CO., LTD	& Co. KG	
Product Codes	ELC Ultrasonic Scaler		Same
Regulation Number and Regulation Name	872.4850 Ultrasonic Scaler		Same
Indications for use	The Integrated Endo System is dental device which combine in a single main control unit an endo motor to clean the root canal, a dental obturator to fill and pressurize, an electronic apex locator to assist the operator to locate the file tip in the root canal and an ultrasonic-handpiece for root-canal cleaning and preparation. The Integrated Endo System is intended solely for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.	The EndoPilot^2 systems are dental devices which combine in a single control unit an endo motor to clean the root canal, a dental obturator to fill and pressurize, an electronic apex locator to assist the operator to locate the file tip in the root canal and an ultrasonic-handpiece for rootcanal cleaning and preparation. The EndoPilot^2 is intended solely for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.	Same
Components	Control-Unit: Meet Endo-II main unit with integrated ultrasonic module with connecting soket. Ultrasonic handpiece: Main handpiece Activator working tip Silicone sleeve	Control-Unit: EndoPilot^2 unit with integrated ultrasonic module with connecting socket. (the ultrasonic module is identical to SUPRASSON SP NEWTRON-module) Ultrasonic handpiece: Handpiece (SUPRASSON SPNEWTRON)	Similar The same ultrasonic module is used. The difference in use of the ultrasonic module result out of the connection to the Meet Endo-II

		Universal wrench for ultrasonic tips Ultrasonic handpiece cable Twin wireless foot switch (Single footswitch or optional Twin-type)	
Intermittent operation	None	1 min/3 min (endodontic treatment)	Different The intermittent operation is controlled by operator
Vibration frequency	45±10kHz	27 to 33 kHz	Different This difference does not raise new questions
Activation	By Power switch, Start/Stop button	By footswitch, ON/OFF button	Different This difference does not raise new questions
Cleaning, disinfection, sterilization	ISO 17664-1 ISO 17665-1	ISO 17664 ISO 17665-1	Same
AC/DC Power supply	Battery: 3.7V, 1200mAh	AC: 100-240 V, 50/60 Hz DC: 12 V, 1.5 A	Different The intermittent operation is controlled by operator
Wireless Connection footswitch	None	4.1 Bluetooth	Different The intermittent operation is controlled by operator
Electrical Safety	IEC 60601-1 IEC 80601-2-60	IEC 60601-1 IEC 80601-2-60	Same
Electromagnetic Compatibility (EC)	IEC 60601-1-2 IEC TR 60601-4-2	IEC 60601-1-2 IEC 61000-3 series IEC 61000-4 series (2,3,4,5,6,8,11	Same IEC 60601-1-2:2014+A1:2020 and IEC TR 60601-4-2:2016 tests of subject device have included the relevant standards test of predicate device.

8. Non-Clinical Tests Performed:

To demonstrate the performance of Integrated Endo System and to show substantial equivalence to the predicate device, DENJOY DENTAL CO., LTD completed a number of non-clinical performance tests. Results confirm that the design inputs, function and performance specifications for the device are met. The Integrated Endo System systems passed the testing in accordance with internal requirements, national

standards, and international standards shown below, supporting its performance, and its substantial equivalence to the predicate device.

The following non-clinical testing was provided in this 510(k):

Biocompatibility evaluation per ISO 10993-1 assessed the risk biocompatibility for in vitro cytotoxicity, skin sensitization, and oral mucosa irritation to ISO 10993-5, 10, 23. All tests passed.

Electrical Safety Testing per IEC 60601-1 AND IEC 80601-2-60, PASSED required testing.

Electromagnetic Compatibility Testing per IEC 60601-1-2, IEC TR 60601-4-2, PASSED required testing.

Wireless Coexistence Testing per ANSI/USEMCSC C63.27, AAMI TIR 69, and FCC CFR Title 47 Part 15 Subpart C Section 15.247, PASSED required testing.

Reprocessing validation (cleaning and sterilization) per the FDA Guidance Document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”.

Coupling between handpieces and motors connected to dental units follows ISO 3964 and ISO 14457; all specifications dimension, tolerances and the extraction force requirements were met.

Software verification and validation testing has been completed on a functional level for a Moderate Level of Concern software including system compatibility testing, risk analysis per IEC 62304 and FDA Guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff" to address possible hazards, mitigations, and design considerations pertaining to intentional and unintentional cybersecurity risks associated with the device, PASSED required testing.

Usability engineering testing per IEC 62336-1, Testing of 15 participants was conducted showing that the participants were able to understand the user manual and labeling and were able to safely and effectively use the device.

10. Conclusion

The Integrated Endo System (model Meet Endo-II) has the same indications for use as the predicate device K202906 EndoPilot^2. Any minor differences in the technological characteristics of the subject device when compared to the predicate devices have been successfully evaluated through appropriate performance testing which demonstrates that the subject device, when compared to the predicate device, does not raise any new questions of substantial equivalence. Therefore, the Integrated Endo System (model Meet Endo-II) has been determined to be substantially equivalent to predicate device K202906 EndoPilot^2.