April 13, 2021

Schlumbohm GmbH & Co. KG
% Oliver Eikenberg, PhD
Senior Consultant QA/RA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K202906
Trade/Device Name: EndoPilot^2
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: Class II
Product Code: ELC, EKX, EKR, LQY
Dated: March 2, 2021
Received: March 9, 2021

Dear Oliver Eikenberg:

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,

Bobak Shirmohammadi -S

For Michael Adjodha
Assistant 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)*
K202906

Device Name
EndoPilot²

Indications for Use *(Describe)*
The EndoPilot² 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 root-canal cleaning and preparation.
The EndoPilot² 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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510(k) Summary

K202906

EndoPilot²

1. Submission Sponsor

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2. Submission Correspondent

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Title: Senior Consultant, Quality & Regulatory Affairs

3. Date Prepared

April 12, 2021

4. Device Identification

Trade/Proprietary Name: **EndoPilot²**

Common/Usual Name:	Dental hand instrument
Classification Name:	Ultrasonic Scaler
Regulation Number:	21 CFR 872.4850
Product Code:	ELC Ultrasonic scaler
	EKX direct drive, AC-powered handpiece
	EKR endodontic plugger, root canal
	LQY root apex locator (unclassified),
Class:	Class II
Classification Panel:	Dental

5. Legally Marketed Predicate Device(s)

For the Endodontic unit systems (applicable to all EndoPilot²model variants):
Primary Predicate

Device name: EMS-200
510(k) number: K153285
Manufacturer: Meta Systems Co., Ltd., Korea

For the Ultrasonic Unit (applicable only to EndoPilot²model variant "ultra" and " ultra plus"):
Reference Device

Device name: SUPRASSON P5 NEWTRON
510(k) number: K050895
Manufacturer: SATELEC-ACTEON Group

6. Indication for Use Statement

The EndoPilot² 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 root-canal cleaning and preparation.

The EndoPilot² is intended solely for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.

7. Device Description

The **EndoPilot²** systems, including the models "comfort", "plus", "ultra", "ultra plus" and the model variant under brand "CanalPro Jeni" (marketed by Distributor Coltène/Whaledent Inc. and identical for technical aspects to model **EndoPilot² comfort**) are standalone AC-powered dental control units with a touch display to which multiple hand-held dental handpieces for root canal preparation (Apex measurement, EndoMotor, Ultrasonic handpiece) and/or root-canal filling (DownPack, BackFill handpiece) can be connected.

These multifunctional devices are intended for use by professionals in the dental clinic use environment. Based on the modular concept of these **EndoPilot²** systems different handpieces can be combined with the control unit and different device variants (systems) of the **EndoPilot²**exist. The key hand-held components like handpieces or endodontic tools of the **EndoPilot²** are medical devices commercially available by themselves and have separate FDA registration or clearance for marketing in the US.

8. Substantial Equivalence Discussion

The following tables compare the **EndoPilot²** to the predicate devices EMS-200 and SUPRASSON P5 NEWTRON with respect to indications for use, principles of operation, technological characteristics, components, and performance, and forms the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate devices.

Table 5A – Comparison of Characteristics between Subject Device and Predicate Device EMS-200

Attribute	SUBJECT DEVICE	PREDICATE DEVICE / 510(k) HOLDER (K153285)	Device Comparison
Manufacturer	**Schlumbohm GmbH & Co. KG**	**Meta Systems Co., Ltd.**	
Trade Name	**EndoPilot²**	**EMS-200**	
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)		***Same***
	872.4850 Ultrasonic scaler ELC Ultrasonic scaler	NA	***See second predicate in Table 5B***
Indications for Use	The EndoPilot² 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 root-canal cleaning and preparation. The EndoPilot² is intended solely for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.	The EMS-200 is a dental device which combines in a single LCD unit an endo motor which ablates the tooth to expand the root canal, a dental obturator to fill and pressurize various shaped packaging elements and an electronic apex locator which assists the operator the location of the front tip in the root canal, for use by trained dental professionals.	***Similar*** *The difference in indications for use result out of the different design and modules used for both devices. The intended use is the same.*
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: 100-240 V, 50/60 Hz DC: 12 V, 1.5 A	AC: 100-240 V, 50/60 Hz DC: 12 V, 5.0 A	***Similar*** *Small DC difference results out of the lower power consumption for EndoPilot² system power adapters*
Battery Operated	Yes, Li-Ion battery, 7.2 V, power output 48 Wh	no	***Different*** *Battery tested for IEC 62133 and an UN 38.3 Test*

Attribute	**SUBJECT DEVICE**	**PREDICATE DEVICE / 510(k) HOLDER (K153285)**	**Device Comparison**
Manufacturer	**Schlumbohm GmbH & Co. KG**	**Meta Systems Co., Ltd.**	
Trade Name	**EndoPilot²**	**EMS-200**	
Components for systems	1) Control unit with display panel (touch screen), 5 connecting sockets, a microSD slot, power supply and wireless foot switch 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 indicator 6) BackFill handpiece (K042828) 7) Ultrasonic handpiece, Ultrasonic Module (K050895)	1) Control unit with display panel (touch screen), 4 connecting sockets, power supply 2) Electronic apex locator and accessories (lip holder, cable assembly and 2 kinds of file holder). 3) Contra-angle for apex measurement 4) Endodontic-motor Handpiece with apex measuring contact 5) Obturation Unit (K031664) 6) BackFill handpiece included in Obturation Unit (see 5) 7) NA	***Similar*** *The small differences in design do not raise new questions of substantial equivalence*
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 17664/17665-1*
Electrical Safety	IEC 60601-1	IEC 60601-1	***Same***
Protection type and level against electric shock	Class II equipment, Type BF applied part	Class I equipment, Type B applied part	***Similar*** Equivalent technology is used,
Electromagnetic Compatibility Electric Safety Tests	IEC 60601-1-2 IEC 61000-3 series IEC 61000-4 series (2,3,4,5,6,8,11) IEC 80601-2-60	IEC 60601-1-2 IEC 61000-4 series (2,3,4,5,6,8,11)	***Similar***
Technological comparison of System Component Functions			
Control 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, stand	***Similar***
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	Single wireless footswitch or optional Twin wireless foot switch	NA, Function is started by pressing a switch by finger	***Different*** *The foot switch provides different method to start the device.*
Wireless connection/Bluetooth	2.402-2.480 GHz, TX Power: +7 dBm	NA	

Attribute	**SUBJECT DEVICE**	**PREDICATE DEVICE / 510(k) HOLDER (K153285)**	**Device Comparison**
Manufacturer	**Schlumbohm GmbH & Co. KG**	**Meta Systems Co., Ltd.**	
Trade Name	**EndoPilot²**	**EMS-200**	
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	Electronic apex locator (Schlumbohm)	Electronic apex locator	***Same***
Apex cable set components (material)	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)	Lip holder (Stainless steel) 64 mm 2 mm File holder B (Silicone rubber & PBT),With cable Length 68 mm , Diameter 9.5 mm Probe cord (PVC), 1.8 m twin cable No retainer	***Similar*** *Same material used for main components 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	ø20 x 94 mm, Weight 52.0g Torque range: Max. 5 Ncm +/- 10% (Gear ratio: 1:1)	ø16.7 x 63 mm, Weight 34.8g Torque range: 0.6 ~ 6.4 Ncm Contra Angle: ACL (B) – 42EP (Gear 16:1)	***Similar***
Mode of Operation:	Forward and reverse		***Same***
Material	Hard chrome plated brass	Hard chrome plated aluminum Stainless steel	***Similar***
Accessories (Endo Files)	Database with preset values for parameters for selected Endodontic Files from File-manufacturers	Database for parameters for selected Endodontic Files	***Similar***

Attribute	SUBJECT DEVICE	PREDICATE DEVICE / 510(k) HOLDER (K153285)	Device Comparison
Manufacturer	**Schlumbohm GmbH & Co. KG**	**Meta Systems Co., Ltd.**	
Trade Name	**EndoPilot²**	**EMS-200**	
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	ø21 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	ø20 x L 108 mm Weight 106 g (including wire) File Rotation Speed : 250-800 rpm Torque limit value : 0.6-5.0 Ncm Gear ratio 16: 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	Plastic, aluminum, stainless steel	***Similar***
Obturation Unit Back (DownPack, BackFill handpiece, Gutta Percha)			
Function	fill and pressurize various shaped packing elements (Gutta percha)		***Same***
Reference to FDA-cleared component	K042828, Obtura Heated Gutta Percha System, by YOUNG OS LLC	K031664 Endodontic Obturation Unit by Sybron Endo	***Similar***
Functional Specification	Manual DownPack handpiece Ø14 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) ø Heating 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	Electronic DownPack handpiece ø27 x L 212 mm, weight 200 g Working temperature up to 300 °C adjustable Pack tip (5 sizes) Electronic BackFill handpiece (K031664) Ø 20 x L 153 mm, weight 104 g Working temperature up to 200°C, adjustable BackFill Needle Diameter:23 gauge and 25 gauge working length 25 mm	***Similar*** *The difference in use (manual, electronic) is verified in the respective 510(k), Design is similar, working temperature is identical.*

Table 5B – Comparison of Main Characteristics between Subject Device and Predicate Device SUPRASSON P5 NEWTRON (this Ultrasonic Unit is only included in EndoPilot² variants "ultra" and "ultra plus")

	SUBJECT DEVICE	PREDICATE DEVICE / 510(k) HOLDER (K050895)	Device Comparison
Manufacturer	**Schlumbohm GmbH & Co. KG**	**SATELEC-ACTEON GROUP**	
Trade Name	**EndoPilot²**	**SUPRASSON P5 NEWTRON**	
Product Codes	ELC Ultrasonic scaler		***Same***
Regulation Number and Regulation Name	872.4850 Ultrasonic Scaler		**Same**
Indications for Use	The EndoPilot² systems are a 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 root-canal cleaning and preparation. The EndoPilot² is intended solely for use by trained dental professionals in professional health care facilities on patients that need root-canal-treatment.	The SUPRASSON P5 NEWTRON is a multi-purpose piezoelectric ultrasonic generator: it is an upgraded generation of the SUPRASSON P5 Booster Piezoelectric Ultrasonic Scaling Generators from SATELEC which received 510(k) clearance for dental applications (K961158) on May 23, 1996, including the technology of the SP NEWTRON module which received 510(k) clearance fordentalapplications (K033764) on March 1, 2004. The SUPRASSON P5 NEWTRON maintains all the functions and the key components of the SUPRASSON P5 Booster and SP NEWTRON Module; it is a stand-alone device manufactured by SATELEC, all with the same components and materials used in the manufacture of the original SUPRASSON P5 Booster and SP NEWTRON module. The intended use, technical performance, and clinical indications are equivalent to those of their predicate devices, the SUPRASSON P5 Booster (K961158) and SP NEWTRON Module (K033764). The SUPRASSON P5 NEWTRON consists of three main components: the ultrasonic handpiece instrument, the control panel case, and the footswitch.	***Similar*** *The difference in intended use result out of the different design and modules used for both devices.* *The SUPRASSON P5 NEWTRON is a standalone device while the ultrasonic module in the EndoPilot² is connected through the control unit.*

	SUBJECT DEVICE	**PREDICATE DEVICE / 510(k) HOLDER (K050895)**	**Device Comparison**
Manufacturer	**Schlumbohm GmbH & Co. KG**	**SATELEC-ACTEON GROUP**	
Trade Name	**EndoPilot²**	**SUPRASSON P5 NEWTRON**	
Components	Control-Unit: EndoPilot² unit with integrated ultrasonic module with connecting socket. (the ultrasonic module is identical to SUPRASSON SP NEWTRON-module) Ultrasonic handpiece: Handpiece (SUPRASSON SP NEWTRON) Universal wrench for ultrasonic tips Ultrasonic handpiece cable Twin wireless foot switch (Single footswitch or optional Twin-type)	Control-Unit SUPRASSON P5 NEWTRON Ultrasonic handpiece: Handpiece (SUPRASSON SP NEWTRON) Universal wrench for ultrasonic tips Ultrasonic handpiece cable Footswitch with cord Single footswitch	***Similar*** *The same ultrasonic module is used. The difference in use of the ultrasonic module result out of the connection to the* EndoPilot² *system*
Intermittent operation	1 min/3 min (endodontic treatment)	5 min/10 min (endodontictreatment)	***Similar***
Vibration frequency	27 to 33 kHz	27 to 33 kHz	***Same***
Activation	By footswitch, ON/OFF button		***Same***
Cleaning, disinfection, sterilization	ISO 17664 ISO 17665-1	ISO 17665-1 ISO 17665-2	***Similar*** *State of the art reprocessing standards are met*
AC/DC Power supply	AC: 100-240 V, 50/60 Hz DC: 12 V, 1.5 A	AC: 110 V or 220/230 V, 50/60 Hz	***Similar*** *only minor difference in design; testing shows no new questions raised.*
Wireless Connection Footswitch	4.1 Bluetooth	NA	***Different*** *State of the art Bluetooth standards demonstrating compliance.*
Electrical Safety	IEC 60601-1	IEC 60601-1	***Same***
Electromagnetic Compatibility (EC)	IEC 60601-1-2 IEC 61000-3 series IEC 61000-4 series (2,3,4,5,6,8,11)	IEC 60601-1-2 (no further information available)	***Similar*** *Additional testing demonstrate compliance to EC*

9. Non-Clinical Performance Data

To demonstrate the performance of **EndoPilot²** and to show substantial equivalence to the predicate device, Schlumbohm GmbH & Co. KG completed a number of non-clinical performance tests. Results confirm that the design inputs, function and performance specifications for the device are met. The **EndoPilot²** 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.

- Biocompatibility evaluation per ISO 10993-1 assessed the risk for biocompatibility testing for cytotoxicity, sensitization and irritation to ISO 10993-5, 10; PASSED
- Electrical safety testing per IEC 60601-1 and IEC 80601-2-60, PASSED required testing
- Electromagnetic Compatibility testing per IEC 60601-1-2 and IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8, IEC 61000-4-11, 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 dimensions, 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 62366-1, PASSED
- Risk Management per EN ISO 14971, all requirements were met and risks reduced as far as possible.

10. Statement of Substantial Equivalence

The **EndoPilot²** systems have the same indications for use as the predicate devices EMS-200 and SUPRASSON P5 NEWTRON. 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 **EndoPilot²** systems have been determined to be substantially equivalent to predicate devices EMS-200 and SUPRASSON P5 NEWTRON.