



Food and Drug Administration
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August 12, 2016

Meta Systems Co., Ltd.
c/o Ms. Yolanda Smith
Consultant
Smith Associates
1468 Harwell Ave
Crofton, Maryland 21114

Re: K153285

Trade/Device Name: EMS-200
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: Class I
Product Code: EKX, EKR, LQY
Dated: July 12, 2016
Received: July 13, 2016

Dear Ms. Smith:

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 yours,

Michael J. Ryan -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

Indications for Use

510(k) Number (if known)

K153285

Device Name

EMS-200

Indications for Use (Describe)

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 packing 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.

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

SPONSOR

Company Name: Meta Systems Co., Ltd.
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 Gyeonggi-do, Korea,
 Telephone: +82 2 2627 3765
 Contact Person: Ray Jeon

Summary Preparation Date: August 8, 2016

DEVICE NAME

Trade Name: EMS-200
 Common/Usual Name: Dental Handpiece and Accessories
 Classification Name: Dental Handpiece and Accessories
 Regulation Number: 21 CFR 878.4200
 Product Code: EKX
 Device Class: Class 1

PREDICATE DEVICE

Primary Predicate:

K Number	Device Name	Manufacturer
K133298	Endo-Smart ES-100	Metabiomed (S-Denti)

Reference Predicates

K Number	Device Name	Manufacturer
K112508	I-Root 100 Electronic Apex Locator	S-Denti Co, Ltd
K031664	Endodontic Obturation Unit	Sybron Endo

DEVICE DESCRIPTION

The EMS -200 dental unit is device that combines the 1) Endo-motor Handpiece (K133298) which ablates the tooth to expand the root canal, a 2) Endodontic Obturation Unit which is used to fill and pressurize various shaped packing elements, and 3) Electronic apex locator (K112508) which is used to ensure the location of the front tip in root canal through changes of electric resistance value into one unit. The working of each of the components is displayed through a single touch screen.

The EMS 200 unit is supplied as follow:

Model	EMS-200S	EMS-200C
Description	Stand Alone unit for portability	Combined with a rolling cart
Components	Display panel- Control unit Handpieces (Micro-motor, Pack and Fill) Additional accessories: File holder A/B, Lip holder, Contra-angle,	Display panel- Control unit Handpieces (Micro-motor, Pack and Fill) Additional accessories: File holder A/B, Lip holder, Contra-angle,

	Pack tip, Fill needle Stand for the unit	Pack tip, Fill needle Cart
Power supply	Adapter & Power cord	Adapter & Power cord Battery

EMS – 200 System Critical Components Description

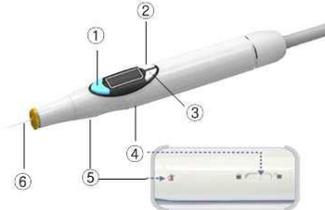


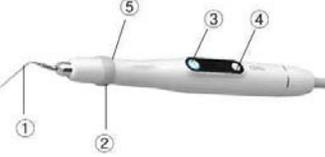
Item	Description	K Number of previously cleared Meta System devices
1. Touch Screen	7" LCD Touchscreen for display of working components	
2. Apex	Electronic Apex Locator Micro signals consisting of dual frequencies coming from the main body return to where they are sent after traveling along the electric circuit that is composed of " main body – probe cord – file holder – hand file – patient – lip holder – probe cord"	K100450
3. Motor	Endo motor (Endodontic motor) Endo motor forms a root canal by rotating the rotary file	K133298
4. Pack	Gutta percha Obturator	
5. Fill	Continuous wave is essentially a vertical compaction (Down-packing) of core material and sealer in the apical portion of the root canal using commercially available heating devices and then back filling the remaining portion of the root canal with thermoplasticized core material using injection device.	
6. Cart	Movable cart for the EMS200C	

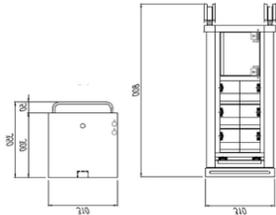
Critical Components Specifications

1. Control Unit with LED Touch Screen	
Dimensions	Control box- 128 mm × 192 mm × 49 mm, Stand type - 253.mm × 13mm × 212.7mm
Weight	< 2kg
2. Apex Locator (K112508)	
Accuracy of Apex Locating point	< ±0.5mm
Accessory	Lip holder, File holder A/B, Probe cord

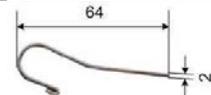
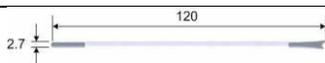
3. Motor: Endo-Motor handpiece (K133298)	
Dimensions	ø20 x L108mm
Weight	106 g (including tubing wire)
Torque range	0.6 ~ 6.4Ncm (Gear 16:1 basis)
Mode of Operation	Auto Stop / Forward and reverse
Gear ratio	16:1
Contra Angle	ACL (B) – 42EP 16:1

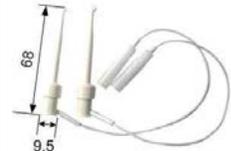
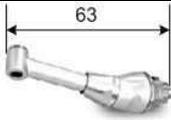
4. Fill: Back Filling handpiece 1.Operation Button 2. Power buttons 3 Mode button 4. Hold switch 5. GP (Gutta Percha) 6.Cartridge	
Dimensions	ø27 x L212mm
Weight	200g
Working temperature	140°C, 160°C, 180°C, 200°

5. PACK: 1. Pack tip 2. Operation button 3. Power Button 4. Mode button 5. Operation lamp	
Dimensions	ø20 x L153mm
Weight	104g
Working temperature	140°C, 200°C, 300°C

6. Cart (Optional)	
Dimensions	310mm x 350mm x 80mm
Weight	26kg

Accessories

Name	Photo	Dimensions & weight	Material
Lip holder		64mm 2 mm Weight – 2g	Stainless steel
File holder A		120mm x 2.7mm Weight - 3g	Silicone rubber & Stainless steel

File holder B		6mm × 9.mm Weight - 4g	Silicone rubber & PBT
Contra angle		∅16.7 x L6mm Weight -34.8g Gear ratio 16:1	Stainless steel
Pack tip		5mm × 2mm Weight -3g	Stainless steel
Fill Needle		56mm Weight – 1g	Brass, Ag plating (or Au plating)
Probe Cord		1,810mm ±3mm Weight 26g	PVC

INDICATIONS FOR USE

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 packing 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.

COMPARISON OF TECHNICAL CHARACTERISTICS

	New device EMS - 200	Primary Predicate Device K133298	References Predicate K112508	Reference Predicate K031664
Manufacturer	Meta Systems	S- Denti Co, Ltd (=Meta Systems) Applicant : Meta Biomed	S- Denti Co, Ltd (=Meta Systems)	Sybron Endo
Trade Name	EMS-200 (model: EMS-200S, EMS-200C)	Endo Smart, ES-100	I-Root 100 Electronic Apex Locator	Endodontic Obturation Unit
Product Code	EKX	EKX	LQY	EKR
510(k) no.	New device	K133298	K112508	K031664
Classification	Class 1	Class 1	None	Class 1
Regulation No.	872.4200	872.4200	None	872.4565

<p>Indications for Use</p>	<p>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 packing 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.</p>	<p>The Endo Smart ES- 100 Endo Motor is indicated for use in standard endodontic procedures using rotary endodontic files and rotary endodontic drills.</p>	<p>The i-Root 100 is intended for measuring the length of the root canal for the purpose of performing root canals and related dental procedures</p>	<p>The Elements Obturation Unit is intended to be used in Dentistry to:</p> <ol style="list-style-type: none"> 1. Provide continuous heat at the tip of a dental instrument to test tooth response to thermal stimulus 2. For tissue cauterization and coagulation, and 3. TO backfill and downpack gutta percha during Endodontic root canal treatment. 4. When in Extruder mode, the Elements Obturation Unit is used only to backfill gutta percha during root canal obturation.
<p>Principle of Operation</p> <p>MOTOR</p> <p>APEX</p> <p>PACK</p> <p>FILL</p>	<p>The Motor rotates the motor-operated file(Ni-Ti file) by pressing the operation button on the micro-motor handpiece which expands or shapes the root canal by using the rotating power of the electric file (Ni-Ti file).</p> <p>Micro signals consisting of dual frequencies coming from the main unit return to where they are sent after travelling along the electric circuit that is composed of 'main unit – probe cord – file holder– file – patient – lip holder – probe cord'.</p> <p>Pack handpiece provides instantaneous heating and cooling of the heat plugger with precisely controlled temperature and timing.</p> <p>FILL handpiece is designed to inject warmed Gutta percha that is specially formulated into the root canal directly.</p>	<p>The Motor rotates the motor-operated file(Ni-Ti file) by pressing the operation button on the micro-motor handpiece which expands or shapes the root canal by using the rotating power of the electric file (Ni-Ti file).</p>	<p>Micro signals consisting of dual frequencies coming from the main unit return to where they are sent after travelling along the electric circuit that is composed of 'main unit – probe cord – file holder– file – patient – lip holder – probe cord'.</p>	<p>Pack handpiece provides instantaneous heating and cooling of the heat plugger with precisely controlled temperature and timing.</p> <p>FILL handpiece is designed to inject warmed Gutta percha that is specially formulated into the root canal directly.</p>

Patient Contacting Materials	Lip holder Pack tip Fill needle		Lip holder	Pack tip Fill needle
Functional Specification	[MOTOR] File Rotation Speed : 250-800rpm Torque limit value : 0.6-5.0Ncm Gear ration 16: 1 (contra angle) [APEX] Accuracy (Working length) : less than ± 0.5 mm [PACK] Pack tip : 140, 200, 300°C [FILL] Heater bobbin : 140, 160, 180, 200°C	[MOTOR] File Rotation Speed : 250-800rpm Torque limit value : 0.6-6.4Ncm Gear ration 16: 1 (contra angle)	[APEX] Accuracy (Working length) : less than ± 0.5 mm ± 0.5 mm	[PACK] Pack tip: 30-600°C [FILL] Heater bobbin: 200°C
Display	LCD touchscreen	LCD	LCD	LCD
Power supply	AC100-240V, 50/60Hz (AC/DC Adaptor) DC 12V, 5.0A	DC7.2V (Li-ion battery)	DC4.5V (Alkaline battery 3ea)	AC100-240V, 50/60Hz
Operating Temperature Humidity:	10°C – 40°C 30%-75%	10°C – 40°C 30%-75%	10°C – 40°C 30%-75%	10°C – 35°C 30%-75%
Dimension Main Body	148.1mm x 187.6mm x 45mm	110mm x 100 mm x 117mm	110mm x 134 mm x 116.5 mm	158mm x 178 mm x 140mm
Weight	Less than 2kg (Stand type)	320g	443g	1.3kg

PERFORMANCE DATA

Safety Testing

- IEC 60601-1:2005 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Medical electrical equipment Part1-1: General requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic compatibility
- ISO 10993-1:2009 Biological evaluation of medical devices-Part 1
- ISO10993-10:2010 Biological evaluation of medical devices-Test for irritation and sensitization
- EN 60601-1-6:2010 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability
- EN 62304:2006 Medical device software. Software life-cycle processes

- EN 60601-1-6:2010 Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability
- EN ISO 14971:2012 Medical devices - Application of risk management to medical devices
- EN 1639:2009 Dentistry. Medical devices for dentistry. Instruments
- EN 62366:2008 Medical devices. Application of usability engineering to medical devices
- EN 1041: 2008 Information supplied by the manufacturer with medical devices
- EN 980:2008 Graphical symbols for use in the labeling of medical devices
- ISO 9001:2008 Quality management systems - Requirements
- ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the validation of a sterilization process
- Sterilization validation per ISO 17665-1 and ISO 17665-2 Sterilization validation was performed to demonstrate SAL of 10^{-6}
- Software documentation and validation for software of moderate level of concern per the FDA Guidance Document for Software Contained in Medical Devices
- Bench testing for conformance to ISO 14457
- Referenced literature articles regarding the temperature of gutta percha to include:
Obturation of Root Canal Systems, American Association of Endodontists; and Dentistry-Thermoplasticized root canal obturating material

CONCLUSION

The EMS-200 is a dental device that combines in a single device with a LCD touchscreen display an 1) endo motor which ablates the tooth to expand the root canal, 2) an electronic apex locator which assists the operator in the location of the front tip in the root canal for used by trained dental professionals, and 3) a dental obturator to fill and pressurize various shaped packing elements.

The Indications for Use for the EMS-200 has expanded to include the Indications for Use of the each predicate.

Similarities between the Motor Handpiece in EMS-200 and the ES-100 (K133298)

The subject device, EMS 200 is similar to the ES-100 (K133298)

- Indications for use for the use of this designated handpiece in the combined units EMS-200
- Operating Principle has not been altered or changed
- Performance Specifications has not altered

Differences

- user interface

Similarities between the Apex in EMS 200 and the predicate i-Root 100 (K112508)

- Indications for use for the use of this designated handpiece in the combined units EMS-200
- Operating Principle has not been altered or changed
- Performance Specifications has not altered

Differences

- user interface

Similarities between the Pack & Fill in EMS 200 and the predicate Elements Obturation Unit (K031664)

- Indications for use for the use of this designated handpiece in the combined units EMS-200
- Operating Principle has not been altered or changed

Differences

- Most of functional uses are similar but the Pack in the EMS-200 is able to choose one of temperature of 140, 200, 300°C and Elements Obturation Unit is able to choose 30°C to 600°C
- In case of Fill in the EMS-200 offers temperature selection of 140, 160, 180, 200°C but Elements Obturation Unit offers only 200°C
As noted above, EMS-200 and Elements Obturation Unit (EOU) have minor differences in terms of performance. However, in terms of safety EMS-200 has safer effects on human due to it operated in the low temperature range than Elements Obturation Unit.
- User interface

The Indications for Use and intended use of the EMS-200 and the predicates has not been altered by the combination of the individual units into a single integrated unit. The technological characteristics for use and function are similar to the primary predicate and the reference predicates provided in this comparison table.

The EMS-200 performance was verified by a comparative bench test with the predicate devices according to ISO 14457. Usability testing by the intended user was performed to validate the user interface of the combined unit. Software documentation and validation for software of moderate level of concern was performed per the FDA Guidance Document for Software Contained in Medical Devices. Electrical Safety testing was performed according to IEC 60601-1:2005 Medical electrical equipment Part 1: General requirements for basic safety and essential performance and IEC 60601-1-2:2007 Medical electrical equipment Part 1-1: General requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic compatibility to verify safe use. All testing was performed for mitigation of risk according to ISO 14971:2012 Medical devices - Application of risk management to medical devices. In addition biocompatibility testing according to ISO 10993-1 was performed on patient contacting materials.

It is the conclusion of Meta Systems, based on non-clinical testing that the EMS-200 introduces no new issues of safety and efficacy and is substantially equivalent to the primary predicate and reference predicate devices.