October 20, 2021

Meta Systems Co., Ltd.
Hyejin Park
RA Staff
#1214-18, Sicox tower 12F, 484, Dunchon-daero,
Jungwon-gu, Seongnam-si, Gyeonggi-do, 13229
KOREA

Re: K210789
Trade/Device Name: EQ-PEX
Regulatory Class: Unclassified
Product Code: LQY
Dated: September 13, 2021
Received: September 22, 2021

Dear Hyejin Park:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210789

Device Name
EQ-PEX

Indications for Use *(Describe)*
EQ-PEX is an Electronic Apex Locator designed for use in measuring the working length 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.

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510(K) SUMMARY

K210789

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information:	Meta Systems Co., Ltd. #1214-18, Sicox tower 12F, 484, Dunchon-daero, Jungwon-gu, Seongnam-si, Gyeonggi-do, 13229, Korea Tel: +82-31-731-7377
Establishment Registration Number:	3007663058
Contact Person:	Hyejin Park
Date Summary Prepared:	October 19, 2021
Device Information:	
Trade name(s):	EQ-PEX
Common/Usual Name:	Locator, Root Apex
Classification	Unclassified
Panel:	Dental
Product Code	LQY

Predicate Device Information:

[1] K112508 / I-ROOT 100 / S-Denti Co. Ltd.

Device Description:

EQ-PEX is Electronic Apex Locator and accessories to be used to treat of patients. It consists of the main body and lip hook, probe cord and 2 kinds of file holder. The device is used to track the position of the file in the root canal based on the impedance of two different frequencies. The device is intended for measuring the length of the root canal during root canal treatments. The components of the device include the main body, probe cord, lip book, file holder, AC adapter, and power cord.

The screen displays measurement information of the root canal length at the current location of the file and displays a number and graph. Stainless steel hand files are intended to be used with the subject device. Lip hook is intended to be placed on the opposite lip of the tooth to be worked on. The file is slowly inserted into the root canal. When the file approaches the apex reference value and alarm will beep and the text apex will appear on the measurement screen.

Indications for Use:

EQ-PEX is an Electronic Apex Locator designed for use in measuring the working length of root canals.

Comparison to Predicate Device(s):

Item	Proposed Device	Predicate Device(s)	Similarities/ Differences
Product name	EQ-PEX	I-ROOT 100	-
Manufacturer	Meta Systems Co., Ltd.	S-Denti Co. Ltd.	---
Establishment Registration Number	3007663058	---	----
510(k) number	K210789	K112508	---

Product code	LQY	LQY	Identical to predicate devices
Classification	Unclassified, Dental	Unclassified, Dental	Identical to predicate devices
Principle of operation	The position of the file in the root canal is expressed by the ratio of the impedances of two different frequencies.	The position of the file in the root canal is expressed by the ratio of the impedances of two different frequencies.	Identical to predicate devices
Intended Use	EQ-PEX is an Electronic Apex Locator designed for use in measuring the working length of root canals.	i-ROOT 100 is intended for measuringthe length of the root canal for the purpose of performing root canals and related dental procedures.	Similar to predicate devices
Usage	Prescription Use	Prescription Use	Identical to predicate devices
Technical Specification			
Power	Internally Powered equipment Rechargeable Lithium ion Battery (3.6Vdc)	1.5V AA x 3	The battery power of the EQ-PEX and I-ROOT 100 has different. However, EQ-PEX achieves its intended use based on the same technology and principles of operation as the predicate device I-ROOT 100.
Display	LCD	LCD	Identical to predicate devices
Accuracy of Apex	<±0.5mm	<±0.5mm	Identical to predicate devices
Size	W 90 mm x D 75.4 mm x H 73.6 mm	W 110 mm x D 100 mm x H 117 mm	The exterior design of EQ-PEX and I-ROOT 100 is different. However, the structure of connecting the probe cord to the main body and displaying the measuring value on the display are the same.
Component	EQ-PEX body Probe cord 1EA, Lip hook 5EA, File holder gender 1EA, File holder A 1EA, File holder B 2EA, AC/DC adapter 1EA, Power cord 1EA	Main Body, Probe cord 1EA, Lip holder 5EA, File holder A 1EA, File holder B 2EA	Similarity
Mode of operations	Continuous operation	Continuous operation	Identical to predicate devices
Sterility	Autoclave Sterilization (Lip hook, File holder A, File holder B)	Autoclave Sterilization (Lip holder, File holder A, File holder B)	Identical to predicate devices
Applied Standards			
Standards met	IEC 60601-1 IEC 60601-1-2 IEC 80601-2-60 IEC 60601-1-6 ISO 14971 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 11737-1 ISO 11737-2 ISO 17665-1 ISO 7405 IEC 62304	IEC 60601-1 IEC 60601-1-2 IEC 80601-2-60 IEC 60601-1-6 ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 11737-1 ISO 11737-2 ISO 17664	Similar to predicate devices

Materials	SUS 304 Used materials conform to ISO 10993.	SUS 304 Used materials conform to ISO 10993.	Identical to predicate devices
Biocompatibility	Conform to ISO 10993-1	Conform to ISO 10993-1	Identical to predicate devices
Compatibility with environment and other devices.	Conform to IEC 60601-1-2	Conform to IEC 60601-1-2	Identical to predicate devices
Electrical Safety	Conform to IEC 60601-1	Conform to IEC 60601-1	Identical to predicate devices
Mechanical Safety	Conform to IEC 60601-1	Conform to IEC 60601-1	Identical to predicate devices
Radiation safety	Conform to IEC 60601-1-2	Conform to IEC 60601-1-2	Identical to predicate devices
Thermal safety	Conform to IEC 60601-1	Conform to IEC 60601-1	Identical to predicate devices

Summary of the technological characteristics compared to the predicate device

New device is substantially equivalent to the predicate device in its technological characteristics stated in the comparison table as attached.

Performance Testing (Non-Clinical Study)

To be in compliance with electromagnetic safety and compatibility, appropriate study has been applied to the new device in accordance with the following standards.

- EN ISO 14971:2012
- IEC 60601-1:2005 + A1:2012
- EN 60601-1-2:2014
- IEC 80601-2-60:2019
- IEC 60601-1-6:2010/AMD1:2013
- EN ISO 10993-1:2009
- EN ISO 10993-5:2009
- EN ISO 10993-10:2013
- ISO 7405:2018
- IEC 62304:2006 + AMD1:2015

To demonstrate the performance of the EQ-PEX and to demonstrate substantial equivalence to the predicate, the following non-clinical testing was performed:

- Biocompatibility evaluation per ISO 10993-1 assessed the risk for biocompatibility testing for cytotoxicity, sensitization and irritation to ISO 10993-5, 10
- Electrical safety testing per IEC 60601-1 and IEC 80601-2-60
- Electromagnetic Compatibility testing per IEC 60601-1-2
- Reprocessing validation (cleaning and sterilization) per the FDA Guidance Document “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling.”
- Software verification and validation testing has been completed for a Moderate Level of Concern software and software documentation per FDA Guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”
- Comparative performance testing of the accuracy of the apex locator and usability validation.

Conclusion

As stated above, the new device has the same device characteristics as the predicate device. The information provided in this summary concludes that the new device is substantially to the i-ROOT 100.