

K112153 : iRoot 100 mini

APR 26 2012

510(k) Summary [as required by 807.92(c)]

A. Applicant:

-Company name: S-Denti Co.,Ltd

-Address: Rm.607, Byucksan Digital Valley 6, 481-4, Gasan-dong, Geumcheon-gu, Seoul, 153-803, Korea

Tel : +82-2-2627-3765~7 Fax : +82-2-2627-3768 web : www.s-denti.com

-Contact person: Peter Chung 412-687-3976

-Date: July 7th, 2011

B. Proprietary and Established Names:

Trade Name: i-ROOT 100 mini

Common Name: Root Apex Locator

Regulation Name: Root Apex Locator

Regulatory Classification: Unclassified, Dental,

Product Code: LQY

C. Predicate device: i-ROOT(K100450)

D. Device Description

i-ROOT 100 mini is Electronic Apex Locator and accessories to be used to treat of patients. It consists of the main unit and lip clip, Cable assembly and 2 kinds of File holder.

E. Intended use

The i-ROOT 100 mini is intended for measuring the length of the root canal for the purpose of performing root canals and related dental procedures

F. Technological Characteristics:

- The i-ROOT 100 mini is identical with predicate device in the following contents;

Buzzer volume, Signal, Graph, Intended Use, Frequencies used(500 Hz \pm 0.2 Hz, 5 kHz \pm 0.002 kHz), Patient auxiliary current(less than AC 10 μ A), Accuracy(\pm 0.5mm) and Power consumption (less than 0.27VA)

- Difference is as follows;

Predicate device(i-ROOT) uses the built-in rechargeable Lithium-ion batteries (4.1V x 2 pcs) but i-ROOT 100mini uses the alkaline disposable batteries (1.5V AA x 3 pcs).

G. Performance (Safety and Effectiveness Information)

The production and inspection is followed by our documented procedures based on our quality systems - ISO 9001/ ISO 13485/ Medical Device Directives 93/42/EC, which have been assessed by the third party certification bodies of SGS Certification.

I. Conclusion:

The performance tests demonstrated that the i-Root 100 mini is substantially equivalent to the predicate device



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

S-Denti Company, LTD.
C/O Mr. Peter Chung
300 Atwood
Pittsburgh, Pennsylvania 15213

APR 26 2012

Re: K112153
Trade/Device Name: i-ROOT 100 mini Electronic Apex Locator
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LQY
Dated: March 10, 2012
Received: March 16, 2012

Dear Mr. Chung:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 11 2153

Device Name: **i-ROOT 100 mini Electronic Apex Locator**

Indications For Use:

The **i-ROOT 100 mini** is intended for measuring the length of the root canal for the purpose of performing root canals and related dental procedures.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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