K100450

5. 510(k) Summary

[as required by 807.92(c)]

NOV 18 2010

A. **Applicant:**

-Company name: S-Denti Co.,Ltd

-Address: 14F NO1407, Kolon Digital Tower Aston, 505-14, Gasan-dong, Geumcheon-gu, Seoul Korea

-Tel:+82-2-2082-8828Fax : +82-2-2082-8829 web : www.s-denti.com

-Contact person: **Peter Chung** 412-687-3976

-Date: **Dec 28th, 2009**

B. Proprietary and Established Names:

Trade Name: i-ROOT

Common Name:. Root Apex Locator

Ragulation Name: Root Apex Locator

Regulatory Classification: Unclassified, Dental,

Product Code: LQY

C. Predicate device: Navi ROOT(K083901)

D. Device Description

The subject device is a lightweight, fully-automatic, battery operated device that allows a dentist or oral surgeon to locate a patient's anatomical root canal apex and obtain accurate root canal length measurements

E. Intended use

The **i-ROOT** 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 device allows the relative position of a dental file and the apex to be determined electrically. Using a standard dental file inserted into the root canal as an electrode, the device emits very small electrical currents having frequencies of 500 Hz and 5 KHz. The current between the file and mouth is measured at each of these frequencies, and compared, with readout of the relative proximity to the apex appearing on a stabilized meter. The use of two frequencies minimizes errors introduced by blood or other conducting medicinal fluids in the root canal.

G. Performance (Safety and Effectiveness Information)

The i-ROOT has been manufactured and tested to meet the safety requirements of IEC. The i-ROOT complies with IEC 60601-1 Medical electrical equipment - Part 1: General requirements for safety and IEC 60601-1-2:2001, Medical electrical equipment - Part 1: General requirements for safety - Collateral standard: Electromagnetic compatibility -Requirements and tests.

I. Conclusion:

The performance tests demonstrated that i-ROOT is as safe, as effective and performs in a substantially equivalent manner to the predicate device

11.Substantial Equivalence Discussion

11.1 Comparison Table

Product	i-ROOT	Navi ROOT
510K No	-	K083901
Manufacturer	**S-Denti Co.,Ltd**	S-Denti Co.,Ltd
Intended Use	Measurement of the length of the root canal for the purpose of performing root canals and related dental procedures	Identical
Method of calculating	Comparison of impedance at multi frequencies	Identical
Electric Current	Input Current : DC 40 ㎃ Patient auxiliary current : AC 10 ㎃	Less than 10pA
Electrical Power	Lithium-ion Battery 8.2VDC(4.1VDCx2)	DC 4.5V(AA Battery 1.5Vx3EA)
Power consumption	0.33VA	180mW Max(150mW)
Measuring Voltage	80mV	Identical
Frequencies used for comparison	500 ㎐, 5 ㎑	Identical
Time of use	2000 Hr Continuous	Identical
Display	LCD	Identical
Accessory	Probe cord 1EA, Lip holder 5EA, File holder A 1EA, File holder B 2EA, AC adapter 1EA, User manual 1EA, USB Cable 1EA(optional), PC software CD(optional) 1EA	Probe cord 1EA, File holder 2EA,
Accuracy	±0.25mm	Identical
Storage condition - Temperature - Humidity	-20 ~ 70℃ 0 ~ 95%	-10 ~ 60℃ 10 ~ 80RH%
Dimensions(LxWxH)	110mm(W) x 100mm(D) x 117mm(H)	153mm(W) x 138mm(D) x 44mm(H)
Weight	Approx. 372g ± 24g	420g

Conclusion

Based upon the intended use, and upon the similarity of product configuration and administration, it can be concluded the i-ROOTis substantially equivalent to the identified predicate device in terms of intended use, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Tae Kye Nam
S-Denti Company, Limited
505-14, Gasan-Dong, Geumcheon-Gu
Seongnam-City, Seoul
Republic of Korea 153-803

NOV 18 2010

Re: K100450
Trade/Device Name: i-ROOT Electronic Apex Locator
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LQY
Dated: August 18, 2010
Received: October 25, 2010

Dear Mr. Nam:

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,

for

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): K100450

NOV 18 2010

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

Indications For Use:
The **i-ROOT** is intended for measuring the length of the root canal for the purpose of performing root canals and related dental procedures

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number: K100450