K131907

JAN 3 1 2014

DENTSPLY

SECTION 5.
510(k) SUMMARY
for
RAYPEX® 6

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5.1 Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
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York, PA 17405
USA

Contact Person: Helen Lewis
Telephone Number: 717-487-1332
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Date Prepared: January 27, 2014

5.2 Candidate Device Details:

- Trade name/Proprietary Name: RAYPEX® 6
- Common Name: Apex Locator
- Classification Name: Locator, Root Apex
- Product Code: LQY – Locator, ROOT APEX
- Review Panel: Dental
- Device Class: Unclassified (Pre-Amendment)

5.3 Predicate Device Identification:

Device to which substantial equivalence is claimed is BINGO PRO apex locator of Forum Engineering Technologies (96) Ltd. (Israel), 510(k) number K111474.

5.4 Device Description:

RAYPEX® 6 is a dental apex locator intended for precise localization of root canal apex.

The measurements in RAYPEX® 6 are performed utilizing AC signals at two frequencies – 500 Hz and 8 kHz. The frequencies are alternated and not mixed, eliminating the need for signal mixing and frequency discrimination electronic circuits. The patented signal measuring method utilized in RAYPEX® 6 is based on measurements of RMS (Root Mean Square) level of the signal.

Advanced user interface implemented in RAYPEX® 6 is based on high resolution touch TFT (Thin Film Transistor) color graphic display with touch panel. RAYPEX® 6 provides clear real time presentation of endodontic file movement inside the canal.

RAYPEX® 6 shows the movement of the file inside the canal from the beginning of the measurements to the end, providing uninterrupted feedback to the dentist. File tracking algorithm enables full-scale display of the file movement during the treatment while Apical Zoom feature enables high-resolution indication of the file advance in pre-apical and apical zones. Large, clearly recognizable graphical readings in Apical Zoom are designed to enable precise control over the file advance matching the individual technique of the dentist. Visual information is accompanied by optional audio signals. The bars shown in the Apical Zoom do not represent actual distance from the apex in mm; they serve as a convenient reference to judge the file tip position in relation to the apex.

Operation of RAYPEX® 6 is fully automatic. no manual calibrations or adjustments are required. The measured signal is analyzed and automatic adjustments are made if required. The device may operate within different conditions in the root canal: dry or wet.

Built-in Demo mode of RAYPEX® 6 enables easy simulation of all stages of the treatment and is designed to simplify familiarization of the user with the device.

Optional verification of proper operation of RAYPEX® 6 is possible through built-in Check mode which enables easy automatic check-up of both the device and its accessories.

For practitioner's convenience the following user interface features may be set through RAYPEX® 6 device setup menu: display background color, preferred sound type and display brightness.

5.5 Indications for Use:

RAYPEX® 6 is a microprocessor controlled device used for locating the apex.

5.6 Substantial Equivalence Comparison

Device Characteristic	**Predicate Device BINGO PRO**	**Proposed Device RAYPEX® 6**
510(k)	K111474	Pending
Device Definition	Electronic apex locator	Electronic apex locator
Device Category	Active, invasive	Active, invasive
Indications for Use	BINGO PRO is an electronic device used for precise apex location and working length determination during root canal treatment. The device enables to obtains correct results in canals with different conditions-dry or wet.	RAYPEX® 6 is a microprocessor controlled device used for locating the apex.
Weight	300g	350g
Where to be used	This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.	This product must only be used in hospital environments, clinics or dental offices by qualified dental personnel.

Device Characteristic	Predicate Device BINGO PRO (K111474)	Proposed Device RAYPEX® 6
Display	3.5" color TFT (portrait orientation)	3.5" color TFT (landscape orientation)
Training mode	DEMO mode is used to demonstrate device operation and to shorten learning curve of the user.	DEMO mode is used to demonstrate device operation and to shorten learning curve of the user.
Check mode	Not available.	"Check mode" built-in feature utilizing dedicated tester allows checking operation of both the device and the accessories.
Power Source	NiMH rechargeable batteries (2.4V)	NiMH rechargeable batteries (2.4V)
Extrenal charge	Input: 120V/50-60Hz Output: 6V DV @ 500mA	Input: AC 100-240V, 50/60Hz Output: 5VDC @ 1,000mA
Automatic Turn-Off function	The device turns off automatically after 5 min. of idle state.	The device turns off automatically after 5 min. of idle state.
Sound indication	Piezzo transducer with sound level control (high, medium, low, mute)	Speaker which enables: -sound level adjustment from mute to high sound level -tone selection
Additional features	Not available	For practioner's convenience user interface setup is available, including selection of: • Display background color • Sound type • Display brightness

5.7 Non-Clinical/Clinical Performance Data

To evaluate the performance of RAYPEX® 6 apex locator, ex-vivo test was performed on extracted teeth. The results obtained with RAYPEX® 6 were compared to the results of the FDA cleared device - BINGO PRO apex locator.

The conclusions of the test were that the measurements of RAYPEX® 6 apex locator are clinically acceptable since they are equivalent to the results of BINGO PRO device and that RAYPEX® 6 measurements in presence of different irrigation liquids are clinically acceptable.

5.8 Conclusion as to Substantial Equivalence

- RAYPEX® 6 has the same intended use and fundamental scientific technology as its predicate device – BINGO PRO (K111474).
- The similarities in the design, indications for use, fundamental product technology, and the results of comparative performance testing support the substantial equivalence of the RAYPEX® 6 to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 31, 2014

DENTSPLY International
Ms. Helen Lewis
Director, Corporate Regulatory Affairs
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Re: K131907
Trade/Device Name: RAYPEX® 6
Regulation Number: Unclassified
Regulation Name: Locator, Root Apex
Regulatory Class: Unclassified
Product Code: LQY
Dated: December 20, 2013
Received: December 24, 2013

Dear Ms. Lewis:

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 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. 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,

Kwame O. Ulmer
-S FDA for

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K131907

Device Name: RAYPEX® 6

Indications for Use:

RAYPEX® 6 is a microprocessor controlled device used for locating the apex.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
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