K073185

MAR - 6 2008

SECTION 5: 510(k) Summary

Submitter

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Contact Person

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Date Prepared

November, 2007

Device Information

Trade name: APX21
Common name: Electronic Apex Locator
Classification Name: locator, root apex
Review Panel: Dental
Product Code: LQY
Device Class: Unclassified (Pre-Amendment)

Devices to which substantial equivalence is claimed:

510(k) number	Trade or propriety name	Manufacturer
K921979	ROOT ZX	J. MORITA USA Inc.

Device Description

The APX21 is an electronic apparatus that employs the bio-impedance principal to estimate the position of an endodontic file in the root canal with respect to the apex point.

Indications for Use

The APX21 is indicated for root canal and other related dental procedures, to be used by a trained professional in general dentistry.

Performance

Prof. Pierre Machetou, who is renowned worldwide for his expertise in Endodontics, has tested the APX21 device in his clinic, and noted the following:

- Good ergonomics
- Precision comparable with the RZX on new treatments and re-treatments.
- Good audible signal
- Should preferably be used on wet canal without exception of liquid
- Excellent visibility on the screen

In-Vitro and In-Vivo studies were carried out to evaluate the performance of the new root-APX21. As part of the study, accuracy and stability of the APX21 were compared to those of Morita's Root ZX.
The APX21 proved to be unconditionally stable, while the RZX exhibited inherent instabilities at certain conditions.
The two devices achieved high rate of accuracy, falling well within the acceptable accuracy range criterion of ±0.5. Nevertheless, accuracy rates achieved with the APX21 In-Vivo were higher relative to the Root ZX, especially when unstable readings were taken into account and/or accuracy range criterion was narrowed down to ±0.2.

All system components that come in contact with the treated patient are biocompatible and autoclaveable.

System was Electrical safety and EMC tested per IEC 60601.

Conclusion

Techdent's **APX21**, subject of this submission, constitutes a **safe, reliable and effective** medical device, meeting all the declared requirements of its intended use. Device presents no adverse health effects or safety risks to patients when used as intended.

The **APX21** has the **same intended use and fundamental scientific technology** as its predicate device – **Morita's Root ZX (K921979)**.

The **APX21** was extensively tested – both Bench and Clinically - against its predicate, and was found to be **substantially equivalent**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 6 2008

Techdent Technologies Limited
C/O Mr. Benny Arazy
Chief Executive Officer and President
Arazy Group
Mizpe Aviv, Industrial Park 13
M. P. Misgav 20187
ISRAEL

Re: K073185
Trade/Device Name: APX21 – Electronic Apex Locator
Regulation Number: 21 CFR 872.3630
Regulation Name: Unclassified
Regulatory Class: None
Product Code: LQY
Dated: January 30, 2008
Received: February 11, 2008

Dear Mr. Arazy:

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.

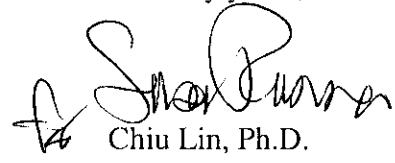
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: Indications for Use

510(k) Number:

Device Name:

APX21 - Electronic Apex Locator

Intended Use:

The APX21 is an electronic apparatus intended to estimate the position of an endodontic file in the root canal with respect to the apex point.

Indications for Use:

The APX21 is indicated for root canal and other related dental procedures, to be used by a trained professional in general dentistry.

Contra Indications:

Do not use the APX21 on patients with implanted heart pacemakers or other equipment which have been warned against use of small electrical appliances.

Prescription Use ___√____ 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)

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

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