K103123

MAR 10 2011

SECTION 5: 510(k) Summary

Submitter

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Date Prepared

October, 2010

Device Information

Trade name: APEX POINTER+
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
K073185	APX21	TECHDENT TECHNOLOGIES, LTD

Device Description

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

Performance

Techdent's **APX21 (K073185)** is an OEM Products of Micro-Mega's **APEX POINTER+** (same design excepted color of external casing) and are both manufactured by Techdent; it is the reason why the performances are identical.

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
- Good precision 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

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

System was Electrical safety and EMC tested per EN 60601.

Conclusion

Micro-Mega's **APEX POINTER+** , 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 **APEX POINTER+** has the **same intended use and fundamental scientific technology** as its predicate device APX21 (Techdent).

The **APEX POINTER+** was compared against its predicate, and was found to be **substantially equivalent**.

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. Conche Philippe
Regulatory Affairs Manager
Micro-Mega Societe Anonyme
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MAR 10 2011

Re: K103123
Trade/Device Name: APEX POINTER+ - Electronic Apex Locator
Regulatory Class: Unclassified
Product Code: LQY
Dated: February 22, 2011
Received: March 3, 2011

Dear Mr. Philippe:

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

SECTION 4: Indications for Use

510(k) Number: K103123

Device Name:

APEX POINTER+ - Electronic Apex Locator

Intended Use:

The APEX POINTER+ 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 APEX POINTER+ 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 APEX POINTER+ 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

510(k) Number: K103123