K132609/5003

JAN 22 2014

Section 5 - 510(k) Summary

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. **Submitter's Identification:**

Essential Dental Systems
89 Leuning Street
South Hackensack, NJ 07606

Date Summary Prepared: December 19, 2013

Contact: Mr. Jeffrey Wan
Contact Email: jwan@edsdental.com
Contact Phone #: 201-487-9090 ext. 118
Contact Fax #: 201-487-5120

2. **Name of the Device:**

Trade name: EDS Ultrasonic Tips
Common name: Scaler, Ultrasonic (Ultrasonic Tips)
CFR Number: 872.4850
Device class: Class II
Product Code: ELC

3. **Predicate Device Information:**

1. Sapphire Plus® Tips, San Diego Swiss Machining, K960889.

4. **Device Description:**

EDS Ultrasonic Tips are an accessory to a piezoelectric ultrasonic handpiece and scaler unit. These powered components are not included as part of the device submitted for application with the 510(k) submission. EDS Ultrasonic Tips are stainless steel and will be available in M3x0.5 and #5-40 thread with 6 different tip designs. 1 tip design is devised for post removal; the remaining 5 tips are designed for negotiating the various angles and directions of root canals.

5. **Intended Use:**

EDS Ultrasonic Tips are intended for use by dental professionals for the removal of soft and hard tissue during endodontic root canal preparation procedures. They can also aid in the removal of endodontic posts and other intra-canal blockages.

6. Comparison to Predicate Devices:

A comparison of the EDS Ultrasonic Tips and the 510(k) cleared Sapphire Plus® Tips indicates the following similarities and differences to the device which received 510(k) clearance:

EDS Ultrasonic Tips are similar to the predicate device Sapphire Plus® Tips in that they are both stainless steel tips used in conjunction with piezoelectric scalers and handpieces to remove soft and hard tissue during root canal preparation procedures.

EDS Ultrasonic Tips are different from the predicate device in the specific design geometry. While they both include a handle with a common attachment to most English and/or Metric piezoelectric units, the contour of the tips differ in thickness, length, and curvature. Furthermore, EDS Ultrasonic Tips are made of a different alloy of stainless steel and do not exhibit a coating.

	Proposed Device	**Predicate Device #1**
510(k)	K132609	K960889
Device Name	EDS Ultrasonic Tips	Sapphire Plus® Tips
Manufacturer	Essential Dental Systems	San Diego Swiss Machining
Intended Use	Remove soft and hard tissue during endo root canal prep. Remove endodontic posts and other intra-canal blockages	Reconstructive dental procedures, crown prep, perio prep, root prep
Composition	316 Stainless steel	13-8 Stainless steel
Operational Principles	Used in conjunction with piezoelectric ultrasonic handpiece and scaler. Ultrasonic energy vibrates tip at high frequencies (up to 40,000 Hz)	Used in conjunction with piezoelectric ultrasonic handpiece and scaler. Ultrasonic energy vibrates tip at high frequencies (up to 40,000 Hz)
Coating(s)	None	Titanium Nitride Zirconium Nitride

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as Follows:

Substantial equivalence of the EDS Ultrasonic Tips to the predicate device is based on a comparison of indications, intended uses, and materials. Mechanical testing was conducted in the form of breakage resistance testing to determine the appropriate shelf life for EDS Ultrasonic Tips.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

EDS Ultrasonic Tips are substantially equivalent to the currently cleared and marketed Sapphire Plus® Tips.

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 22, 2014

Essential Dental Systems
Mr. Jeffrey Wan
Research and Development Manager
89 Leuning Street
South Hackensack, NJ 07606

Re: K132609
Trade/Device Name: EDS Ultrasonic Tips
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: December 19, 2013
Received: December 20, 2013

Dear Mr. Wan:

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.

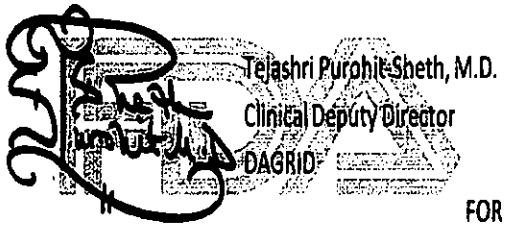
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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



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

510(k) Number (if known): K132609

Device Name: EDS Ultrasonic Tips

Indications for Use:

EDS Ultrasonic Tips are intended for use by dental professionals for the removal of soft and hard tissue during endodontic root canal preparation procedures. They can also aid in the removal of endodontic posts and other intra-canal blockages.

Prescription Use X
(Per 21 CFR 801 Subpart D)

OR

Over the Counter Use ____
(Per 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)

Mary S. Runner -S
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