DEC 1 3 2007

Exhibit #1

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.

The assigned 510(k) number is: K072555

1. **Submitter's Identification:**
   Essential Dental Systems
   89 Leuning Street
   South Hackensack, NJ 07606

   Date Summary Prepared: September 6, 2007

   Contact: Mr. Brian Rasimick

2. **Name of the Device:**

   EDTA Plus

3. **Predicate Device Information:**

   1. SmearClear®, K# 024198, Sybron Dental Specialties, Inc., Orange, CA

   2. Moyco-EDTA, K# 950365, Union Broach, Div. Moyco Industries, Inc. Emigsville, PA

4. **Device Description:**

   EDTA Plus is a root canal cleanser for use in endodontic procedures. During/After endodontic instrumentation, the product should be used to clean the canal space and remove the smear layer before placement of the endodontic filling. The material can be delivered into the canal using a side-vented, closed tip irrigation needle.

   The device consists of a 16 oz. bottle of EDTA Plus, a peach-colored aqueous solution.

5. **Intended Use:**

   EDTA Plus is a root canal cleanser designed to facilitate removal of dentinal debris from the walls of root canals prior to obturation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2007

Mr. Brian Rasimick
Research & Development Manager
Essential Dental Systems, Incorporated
89 Leuning Street, Suite 8
South Hackensack, New Jersey 07606

Re: K072555
Trade/Device Name: EDTA Plus
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: KJJ
Dated: November 28, 2007
Received: November 30, 2007

Dear Mr. Rasimick:

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.

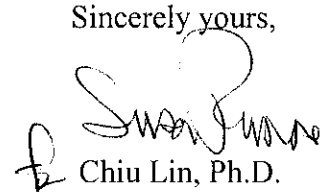
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K072555

Device Name: EDTA Plus

Indications for Use:

EDTA Plus is a root canal cleanser designed to facilitate removal of dentinal debris from the walls of root canals prior to obturation

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)

Susan Runner

...siology, General Ho...,
...l, Dental Devic...

...r K072555