K083516

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510(k) Summary
for OroScience, Inc
Periogenix

1. SUBMITTER/510(K) HOLDER

OroScience, Inc.
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FEB 20 2009

Contact Person: Phil Houle
Telephone: 650-315-7538

Date Prepared: November 25, 2008

2. DEVICE NAME

Proprietary Name:	Periogenix
Common/Usual Name:	Periodontal dressing
Classification Name:	Dental Cement

3. PREDICATE DEVICES

- Coe-Pak Periodontal Dressing, Coe Laboratories, Inc. (K881422)
- Hager Reso-Pac Periodontal Dressing, Hager Worldwide, Inc, (K050658)

4. DEVICE DESCRIPTION

Periogenix consists of thirty (30) disposable, single use dental trays and a canister of topical periodontal paste (TPP). The TPP is dispensed into the single use disposable dental tray, which together provide a moist temporary physical barrier that covers the site of application to avoid further irritation.

5. INTENDED USE

Periogenix is a periodontal wound dressing intended to protect injured periodontal tissue (gums) by forming a temporary physical barrier to avoid further irritation.

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6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The basic design and application of Periogenix and the predicate devices are similar in that they all provide a temporary physical barrier for oral tissues after oral and periodontal surgery. The formulations of the proposed and predicate devices are different, although the difference in formulation does not affect safety or effectiveness since biocompatibility testing and a clinical evaluation have been performed to support the proposed Periogenix.

Both the proposed Periogenix and the Hager Reso-Pac Periodontal Dressings are similar in that they are neutral in smell and taste, ready-to-use, and provide for a temporary physical barrier. Periogenix TPP is dispensed into a dental tray and placed over the affected area of the dental arch three times daily for up to 10 days. After each treatment, the dental tray is removed and discarded. The Hager Reso-Pac is placed on an applicator and then applied to the affected area. The Reso-Pac stays in place for up to 30 hours and slowly dissolves.

The Coe-Pak Periodontal Dressing is slightly different than Periogenix and Reso-Pac in that the Coe-Pak Dressing is a two-part system consisting of a base and a catalyst that are mixed together chair-side by the dentist. After mixing, the paste is molded into the desired shape and packed over the surgical site on the dental arch after surgery. The paste hardens and the packing is left over the surgical site for up to 10 days until the patient returns to the dentist to have the hardened paste removed. Periogenix uses a pre-mixed biocompatible TPP dispensed from a canister into a dental tray which, when placed over the surgical site of the dental arch, provides a temporary physical barrier. In some cases, the dentist may fabricate a custom dental tray specific to the patient's dental arch. The TPP is then dispensed into the custom dental tray and seated over the affected area of the dental arch three times daily for up to 10 days.

Periogenix and the predicate Coe-Pak and Reso-Pac Periodontal Dressings are all provided non-sterile to the user and are indicated for single use.

7. PERFORMANCE TESTING

Biocompatibility, animal, and clinical testing have been performed and have shown that the proposed Periogenix is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OroScience, Incorporated
C/0 Ms. Mary McNamara-Cullinane, RAC
Senior Regulatory Consultant
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

FEB 20 2009

Re: K083516
Trade/Device Name: Periogenix
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: II
Product Code: EMA
Dated: February 12, 2009
Received: February 13, 2009

Dear Ms. McNamara-Cullinane:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K083516

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Indications for Use

510(k) Number (if known):

Device Name: Periogenix

Indications for Use:

Periogenix is a periodontal wound dressing intended to protect injured periodontal tissue (gums) by forming a temporary physical barrier to avoid further irritation.

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

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

510(k) Number: K083516