K063812

Section 9
510(K) SUMMARY

JAN 12 2007

SPONSOR:	Straumann 60 Minuteman Road Andover, MA 01810
CONTACT/SUBMITTER:	Lisa M. Quaglia Regulatory Affairs and Clinical Research Director Tel: (978) 747-2575
DATE OF SUBMISSION:	December 21, 2006
DEVICE:	Straumann® PrefGel
Trade Name: Common Name: Classification:	PrefGel™ Root Surface Conditioning Gel Dental Classified Under 21 CFR Part 872.3690. Classified as a Class II Device.
PREDICATE DEVICE:	PrefGel (K940737)
DEVICE DESCRIPTION:	PrefGel is an EDTA gel used for topical application prior to periodontal surgery to remove the smear-layer.
INTENDED USE:	PrefGel is intended for topical application onto exposed root surfaces during periodontal surgery in order to remove the smear-layer. PrefGel has been shown to effectively remove the smear-layer. PrefGel has also been shown to produce a fibrilliar collagenous meshwork on the exposed and conditioned surface by selective removal of mineral. In addition, PrefGel does not induce any detectable necrosis in the surrounding periodontal tissues.
COMPARISON OF CHARACTERISTICS:	The proposed device is substantially equivalent to currently marketed device. They share the same intended use, same design characteristics, and the same method of application.
PERFORMANCE DATA:	The proposed device is substantially equivalent to the currently marketed PrefGel in terms of performance characteristics tested and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2007

Ms. Lisa M. Quaglia
Regulatory Affairs and Clinical Research Director
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

Re: K063812
Trade/Device Name: PrefGel™
Regulation Number: N/A
Regulation Name: Root Canal Cleanser
Regulatory Class: Unclassified
Product Code: KJJ
Dated: December 21, 2006
Received: December 22, 2006

Dear Ms. Quaglia:

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.

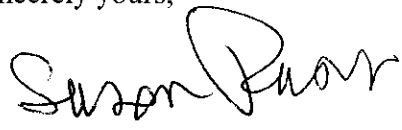
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu S. Lin, PhD
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 Statement

510(k) Number (if known) K063812

Device Name Straumann PrefGel™

Indications for Use The Straumann© PrefGel™ is indicated for topical application onto exposed root surfaces during periodontal surgery in order to selectively remove the smear-layer. PrefGel has been shown to produce a fibrillar collagenous meshwork on the exposed and conditioned root surface by selective removal of mineral. It does not induce any detectable necrosis in the surrounding periodontal tissues.

Prescription Use ___X___ OR Over the Counter Use ____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

General Hos... Services

K063812