K101956

straumann

510(k) SUMMARY

DEC 16 2010

A. Submitter's Information

Name:	Straumann US (on behalf of Institut Straumann AG)
Address:	60 Minuteman Road
	Andover, MA 01810
Phone:	(800) 448-8168, ext 2575
Fax Number:	978-747-0023
Contact Person:	Janet C. Kay, Director Regulatory Affairs

B. Date Summary Prepared: August 17, 2010

C. Device Name:

Propriety Name:	**Straumann MembraGel**
Common/Usual Name:	**Bone grafting material**
Classification Name:	**Barrier, Synthetic, Intraoral**
Classification Number:	**Class II Part 872.3930**
Product Code/Review Panel	**NPK**

D. Predicate Device Name:

- Straumann MembraGel (K082111, 5/22/09)

E. Description of the Device

Straumann® MembraGel is a sterile, synthetic, degradable barrier membrane for single patient use. It is composed of two liquid poly(ethylene glycol) (PEG) compounds forming a hydrogel upon mixing. Straumann MembraGel is applied as a viscous liquid and gels on the application site within approximately 20 to 50 seconds. Straumann MembraGel acts as a barrier that inhibits non-osteogenic soft tissue cells of the overlying soft tissue from entering the defect site thereby supporting undisturbed regeneration of alveolar bone. Degradation of

Straumann MembraGel by hydrolysis starts during normal wound healing. Straumann MembraGel must be stored refrigerated between 2-8°C (36-46°F). The application volume of Straumann MembraGel is 0.8 ml for approximately 5-7cm^2 coverage.

The Straumann MembraGel kit contains:

1. Two glass syringes each filled with a PEG component (PEG A and PEG B) mounted in a plastic holder.
2. Two plastic syringes each filled with an activator (Activator A and Activator B) in a plastic holder.
3. One applicator tip (a static mixer connected to an adapter).

All components are delivered sterile and must be used immediately after opening of the blister packaging in an aseptic surgical environment. See Instructions for use handling instructions.

F. Intended Use of the Device

Straumann MembraGel is a biodegradable, synthetic, in situ forming hydrogel material. It is intended to aid in the regeneration and integration of oral tissue components in guided bone regeneration procedures. This includes the surgical treatment of peri-implant defects, bone defects, deficient alveolar ridges, and extraction sockets. Because MembraGel is not self-supporting, it must be used in combination with a bone graft material in order to maintain space under the membrane.

G. Technological Characteristics

The proposed device is substantially equivalent to currently marketed device. The intended use is the same as the intended use of the predicate device. The proposed MembraGel has the same design and fundamental operating principles as the predicate device. The changes to the material composition had no impact to the final design of the product and remains substantially equivalent to the predicate device, Table 1 demonstrates the technological modifications made to MembraGel compared to the currently marketed predicate device.

Table 1

Features	Modified Straumann MembraGel	Straumann MembraGel K082111
Operating Principle	Straumann MembraGel is applied on the site in liquid form through a syringe applicator	Identical
Physical Properties	Initial swelling of Straumann MembraGel samples meet internal specifications Gelation time of the Straumann® MembraGel kit between 20 and 50s A degradation pattern meets internal specifications including complete degradation of the Straumann MembraGel.	Identical
Tissue Occlusive Properties	Tissue occlusive properties depend on the physical properties of the PEG network, which is governed density of the crosslink. Cell occlusivity is determined by the degradation pattern and time. Thus, tissue occlusive properties were not impacted by this modification.	Identical
Viscosity	The viscosity of the formulation is determined by the Activators present in solution A and B. These solutions were not impacted by the modification described in this 510(k)	Identical
Water uptake of the gelled product	The modified device was required to meet the original specification	Identical

H. Performance Testing

Verification and validation testing were performed to ensure that the Straumann MembraGel functions as intended and that the modification did not impact the essential performance of the MembraGel. The Table 2 describes the testing performed on the MembraGel included:

Table 2

Test performed	Acceptance criteria	Results
Biocompatibility		
Cytotoxicity	Cytotoxic measurements results equal to or less than the predicate	Non-cytotoxic
Acute Systemic Toxicity	Acute Systemic Toxicity results equal to or less than the predicate	Non-toxic
SQ Implantation (4 Weeks) - Rabbits	SQ Implantation results equal to or less than the predicate	Slight Irritant[1]
Gelation time	20-50 sec	Passed
In-vitro water uptake of the gelled product	Less than 20%wt within 4h after gelation	Passed
In-vitro degradation pattern and time	Following a defined degradation kinetics ending in complete disintegration of the MembraGel	Passed

[1]Response noted was typical for similar absorbable materials subcutaneously implanted

I. Conclusion

The results from the testing conducted, demonstrated that the Straumann MembraGel functions as intended and met pre-determined acceptance criteria.

The Straumann MembraGel is a validated system. The results of performance testing, biocompatibility testing, and risk analysis indicate that the Straumann MembraGel is substantially equivalent to the named predicate device.

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

Ms. Janet C. Kay
Director, Regulatory Affairs
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

DEC 16 2010

Re: K101956
Trade/Device Name: Straumann MembraGel™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPK
Dated: December 6, 2010
Received: December 7, 2010

Dear Ms. Kay:

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

K101956

Indications for Use Statement

5l0(k) Number (if known)

Device Name: Straumann MembraGel™

Indications for Use:

Straumann MembraGel is a biodegradable, synthetic, in situ forming hydrogel material. It is intended to aid in the regeneration and integration of oral tissue components in guided bone regeneration procedures. This includes the surgical treatment of peri-implant defects, bone defects, deficient alveolar ridges, and extraction sockets. Because MembraGel is not self-supporting, it must be used in combination with a bone graft material in order to maintain space under the membrane.

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)

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

510(k) Number: K