K123697

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Revised 510(k) Summary for the Matricel GmbH Matricel Dental Barrier Membrane (per 21CFR 807.92)

1. SUBMITTER/510(K) HOLDER

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Date Prepared: July 24, 2013

2. DEVICE NAME

Proprietary Name:	Matricel Dental Barrier Membrane
Common/Usual Name:	Barrier, animal source, intraoral
Classification Name:	Bone Grafting Material (21 CFR 872.3930)
Product Code:	NPL
Device Class:	2

3. PREDICATE DEVICES

- Bio-Gide (Ed. Geistlich Soehne AG fuer Chemische Industrie, K042197 and K050446)
- Ossix™ Plus (ColBar LifeSciences Ltd., K053260)

4. DEVICE DESCRIPTION

The Matricel Dental Barrier Membrane is an intraoral porcine membrane intended to be used in dental applications as a barrier membrane for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR) to support the growth of new tissue and bone. The Dental Barrier Membrane is composed of a network of highly purified porcine collagen (predominantly Type I with some Type III) and elastin fibers.

The Dental Barrier Membrane is offered in three sizes (15x20mm, 25x30mm and 30x40mm) with Rough and Smooth surfaces to accommodate physician preferences. The Smooth version is further processed to achieve a flattened surface, whereas the Rough version retains the natural fibrillar structure of the membrane. The Rough and

Smooth membrane have identical technological, mechanical and chemical characteristics.

The product is packaged in double blister packs and sterilized by ethylene oxide. The Dental Barrier Membrane is supplied sterile and is indicated for single use.

5. INDICATION FOR USE/INTENDED USE

The Dental Barrier Membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier membrane for:

- Ridge augmentation for later implant insertion
- Augmentation around implants placed in immediate/delayed extraction sockets
- Localized ridge augmentation
- Alveolar ridge preservation/reconstruction
- Osseous fill around implants in peri-implantitis bone defects
- Over the window in lateral window sinus elevation procedures
- Intra-bony defects around teeth
- Treatment of recession defects, together with coronally positioned flap
- In furcation defects in multi-rooted teeth.

6. PRINCIPLES OF OPERATION

The process of GTR/GBR is facilitated by the use of resorbable implants such as the Dental Barrier Membrane and legally marketed barrier products, including the predicate devices Bio-Gide (subject of K042197 and K050446) and Ossix™ Plus (subject of K053260). The Dental Barrier Membrane, like the predicate devices, achieves its principal intended action solely by providing a physical barrier to contain the bone graft material at the defect site and to exclude in-growth of surrounding tissue for a period of time long enough to allow bone regeneration to take place.

7. TECHNOLOGICAL CHARACTERISTICS

The proposed Dental Barrier Membrane and the predicate devices Bio-Gide (subject of K042197 and K050446) and Ossix™ Plus (subject of K053260) have substantially equivalent indications for use. These porcine membranes are used to provide a barrier to support GBR and GTR. Both the proposed and predicate devices are derived from porcine tissue and share the similar technological and biochemical characteristics. Specifically, the Dental Barrier Membrane and Bio-Gide membranes contain Type I with some Type III collagen and elastin fibers. Furthermore, the available sizes and weight per unit surface area (surface weight) of the Dental Barrier

Membrane is within the specifications of Bio-Gide. Both the proposed and predicate membranes are resorbable over time.

All membranes are sterile, packaged in double blister packages, and have a shelf life of 3 years. The Dental Barrier Membrane and Ossix™ Plus are sterilized by ethylene oxide and Bio-Gide is sterilized by gamma irradiation.

8. NON-CLINICAL TESTING

Bench testing, consisting of tensile strength, peak denaturation temperature, expansion after wetting were completed to demonstrate that the performance of the Dental Barrier Membrane met specifications. The Dental Barrier Membrane was characterized in accordance with ASTM F2212-11. Biocompatibility testing to ISO 10993-1 was performed to demonstrate the biological safety of the device.

Biostability (enzymatic resistance) testing was performed to assess the potential for degradation due to colonization with dental bacteria. Results demonstrated that the Dental Barrier Membrane behaves as stable as the predicate Bio-Gide when subjected to enzymatic degradation.

Animal testing was performed to compare the resorption characteristics of the proposed Dental Barrier Membrane and the predicate Bio-Gide. Results demonstrate that the two products do not elicit an inflammatory response at the implantation site and exhibit comparable resorption characteristics.

9. CLINICAL TESTING

No clinical testing was submitted in support of this 510(k) premarket notification.

10. CONCLUSIONS

The indications for use, principles of operation, and technological characteristics of the proposed Dental Barrier Membrane are substantially equivalent to the predicate devices Bio-Gide (subject of K042197 and K050446) and Ossix™ Plus (subject of K053260). Differences between the proposed and predicate devices are limited to minor differences in visual appearance, texture of membrane, and sterilization methods. These differences are minor and do not impact the safety and effectiveness of the device.

The safety, performance and effectiveness of the Dental Barrier Membrane for its intended use are demonstrated by bench and animal studies. Based on the evidence provided, Matricel believes that the proposed Dental Barrier Membrane is

substantially equivalent to the predicates.

Table 5-1. Side-by-Side Comparison of Matricel Dental Barrier Membrane with Predicate Devices

	Matricel Dental Barrier Membrane*	**Bio-Gide® (Ed. Geistlich Soehne Ag fuer Chemische Industrie)**	**Ossix™ Plus (ColBar LifeScience Ltd.)**
Regulatory Status	Proposed	K042197, K050446	K053260
Product Code	NPL	NPL	NPL
Intended Use	The Dental Barrier Membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier membrane for: • Ridge augmentation for later implant insertion • Augmentation around implants placed in immediate/delayed extraction sockets • Localized ridge augmentation • Alveolar ridge preservation/reconstruction • Osseous fill around implants in peri-implantitis bone defects • Over the window in lateral window sinus elevation procedures • Intra-bony defects around teeth • Treatment of recession defects, together with coronally positioned flap • In furcation defects in multi-rooted teeth	Bio-Gide® is recommended for: • Simultaneous use of GBR-membrane (Bio-Gide®) and implants; • Augmentation around implants placed in immediate extraction sockets; • Augmentation around implants placed in delayed extraction sockets; • Localized ridge augmentation for later implantation; • Alveolar ridge reconstruction for prosthetic treatment; • Filling of bone defects after root resection, cystectomy, removal of retained teeth; • Guided bone regeneration in dehiscence defects; and • Guided tissue regeneration procedures in periodontal defects.	Ossix™-Plus biodegradable collagen membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as biodegradable barrier for: • Ridge augmentation for later implant insertions. • Simultaneous ridge augmentation and implant insertions. • Ridge augmentation around implants inserted in delayed extraction sites. • Ridge augmentation around implants inserted in immediate extraction sites. • Alveolar ridge preservation consequent to tooth (teeth) extraction(s). • Over the window in lateral window sinus elevation procedures. • In implants with vertical bone loss due to infection, only in cases where satisfactory debridement and implant surface disinfection can be achieved. • In intra bony defects around teeth • For treatment of recession defects, together with coronally positioned flap • In furcation defects in multi rooted teeth
Material Source	Porcine	Porcine	Porcine
Composition	Collagen Types I and III, and elastin	Collagen Types I and III, and elastin	Collagen Type I***
Size	15x20mm, 25 x 30mm, 30 x 40 mm	13 x 25 mm, 25 x 25 mm, 40 x 50 mm	15 mm x 25 mm, 25 mm x 30 mm and 30 mm x 40 mm
Surface weight**	>10 mg/cm^2	>10 mg/cm^2	Data not available
Form	Membrane	Membrane	Membrane
Cross-linking	No	No	Yes
Resorbable	Yes	Yes	Yes
Conformability	The membrane is flexible and conforms to the defect site	The membrane is flexible and conforms to the defect site	The membrane is flexible and conforms to the defect site
Non-pyrogenic	Yes	Data not available	Data not available
Biocompatibility	Yes	Yes	Yes
Sterilization	Ethylene oxide	Gamma radiation	Ethylene oxide
Shelf Life	3 years	3 years	Data not available
Packaging	Double blister package	Double blister package	Double blister package

* The Matricel Dental Barrier Membrane is offered in rough and smooth versions
** Surface weight [weight of the product in mg divided by the surface area in cm^2]
*** Source: http://iadr.confex.com/iadr/2010dc/webprogramcd/Paper129086.html

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

February 24, 2014

Matricel GmbH
Dr. Ingo Heschel
CEO Matricel GmbH
Kaiserstrasse 100
D-52134 Herzogenrath
Germany

Re: K123697
Trade/Device Name: Matricel Dental Barrier Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: February 4, 2014
Received: February 4, 2014

Dear Dr. Heschel:

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

Revised Indications for Use

510(k) Number (if known): K123697

Device Name: Matricel Dental Barrier Membrane

Indications for Use:

The Dental Barrier Membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier membrane for:

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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)

Mary S. Runner -S
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