K103087

AUG 2 6 2011

biom'up
ADVANCED BIOMATERIALS

5. 510(k) Summary, Cova™MAX Resorbable Collagen Membrane for Guided Tissue and Bone Regeneration

Submitter's name and address:	Biom'Up S.A. 8, Allee Irene Joliot-Curie 69800, Saint-Priest, France
Contact person:	Valerie Centis, R&D Project Manager and Regulatory Affairs Biom'up S.A. 8, Allee Irene Joliot-Curie 69800, Saint-Priest, France Phone: +33 (0)4 86 57 36 10 Fax: +33 (0)4 37 69 00 84 Email: regulatory.affairs@biomup.com
Date Summary was prepared:	October 18th 2010
Trade/Proprietary Name:	Cova™MAX
Common/Usual Name:	Resorbable Membrane for Guided Tissue and Bone Regeneration
Classification Name:	Barrier, Animal Source, Dental
Product Code:	NPL
Regulation Number:	21 CFR 872.3930
Device Classification:	Class II
Predicate Devices	BIO-GIDE® (K042197) Ossix™ Plus (K053260)

Device Description

Cova™MAX is a resorbable acellular membrane for guided tissue and bone regeneration in dental applications. Cova™MAX membranes are manufactured using a standardized, controlled process. Each Cova™MAX membrane is fabricated solely from Type I collagen extracted from veterinary certified pig tendon. Porcine tendon is known to be one of the purest sources of Type I collagen that can be readily obtained and processed in commercial quantities. It is packaged in a double package and sterilized by gamma irradiation.

K103087

biom'up
ADVANCED BIOMATERIALS

Cova™MAX membranes serve as a barrier to guide the healing process between anatomic plans of tissues. It has been designed in accordance with the accepted principles or guided bone regeneration (GBR) as a wound healing material post surgery. They are designed to be resorbable, non inflammatory and biocompatible for uses in clinical periodontics.

The Cova™MAX membrane is completely resorbable within a timeframe compatible with the healing process. When wetted, the membrane is conformable, elastic and easy to handle. It can be used alone or, if needed, it can be sutured in place. Cova™MAX is provided in rectangular sheets of 15 x 25 mm, 20 x 30 mm and 30 x 40 mm. Furthermore, the device can be easily trimmed or shaped to the appropriate size, without tearing or fragmenting, to fit the periodontal defect or zone to be treated.

Intended Use

Cova™MAX is intended for use in oral surgical procedures as a resorbable membrane material for use in:

-Simultaneous use of GBR-membrane (Guided Bone Regeneration) 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 and removal of retained teeth;
-Guided bone regeneration in dehiscence defects;
-Guided tissue regeneration procedures in periodontal and recession defects.

Basis for Substantial Equivalence

The intended use, product design, composition, physical structure and target population of Cova™MAX resorbable collagen membranes are substantially equivalent to the FDA cleared and legally marketed predicate devices BIO-GIDE® (K042197) and Ossix™Plus (K053260). Similarities are presented in Table 1.

K103087

biom'up
ADVANCED BIOMATERIALS

Medical Device Name	Cova™MAX	BIO-GIDE®	Ossix™Plus
Origin	Porcine	Porcine	Porcine
Intended use	Used for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus	Used for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus	Used for guided tissue regeneration procedures in periodontal defects to enhance regeneration of the periodontal apparatus
Device characteristics	Membrane-like Easy to manipulate Flexible Implantable Wettable Smooth	Membrane-like Easy to manipulate Flexible Implantable Wettable Smooth	Membrane-like Easy to manipulate Flexible Implantable Wettable Smooth
Biocompatibility	Established	Established	Established
Non pyrogenic	Yes	Yes	n/a
Resorbable	Yes	Yes	Yes
Suturable	Yes	Yes	Yes
Reusable	Single-use device	Single-use device	Single-use device
Shelf-Life	18 months	36 months	36 months
Sterilisation Method	Gamma irradiation	Gamma irradiation	Gamma irradiation
Packaging	Double-peel packages	Double-peel packages	Double-peel packages

Table 1. Cova™MAX and its predicates summarized comparison chart.

Any differences in technological characteristics between the Cova™MAX and the predicate devices do not raise any new issues of safety or efficacy. The performance and safety of the material used was evaluated. The collective results have demonstrated that the Cova™MAX is substantially equivalent to the respective predicate devices with regard to safety and efficacy.

Safety

Biocompatibility studies have demonstrated Cova™MAX to be: non-cytotoxic, non-pyrogenic, non-irritating, and non-sensitizing. The following studies were conducted:

a) Cytotoxicity
b) Dermal Sensitization/irritation
c) Acute Systemic Toxicity
d) Acute Intracutaneous Reactivity
e) Genotoxicity
f) Mutagenecity
g) Pyrogenecity
h) Implantation/Absorption
i) Sub-Chronic/Chronic Toxicity
j) Hemolysis

The Cova™MAX Resorbable Collagen Membrane for Guided Tissue and Bone Regeneration manufacturing process complies with the United States Food and Drug Administration and European Standards for animal tissue sourcing and viral inactivation.

K103087

biom'up
ADVANCED BIOMATERIALS

Summary of Effectiveness Data

Animal Data

Guided Bone Regeneration in periodontics has been proven from animal model studies. That is, during the surgery, a barrier membrane is placed over the wound to prevent contact of connective tissue with the bony surface. Thereby, bone cells can grow into the defect site to fill the space.

A comprehensive literature research showed that numerous materials, including the predicates, have been studied for this use in various animal models. The animal data provided evidence that using equivalent membranes as Cova™MAX as a barrier to aid in wound healing has been verified using resorbable membranes is a valid approach.

Clinical Data

Results from human studies from the literature are consistent with animal studies. Similar to animal studies, resorbable membranes such as Cova™MAX are effective as a barrier to aid in wound healing making its use fully accepted in the clinical practice of periodontics.

It should be noted that the 13-week resorption claim is an estimate from a rat implantation study which was similar to predicate animal studies. An estimation for clinical resorption will need to be made by the clinician based on the known resorption times (6 and 8 months) of similar devices: Bio-Gide® and Ossix™Plus and on experience.

Conclusion

Cova™MAX Resorbable Collagen Membrane for Guided Tissue and Bone Regeneration is substantially equivalent to its predicate devices: BIO-GIDE® and Ossix™Plus.

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. Valerie Centis
R&D Manager and Regulatory Affairs
Biom'Up SA
8, Allee Irene Joliot-Curie
69800,Saint-Priest
France

AUG 26 2011

Re: K103087
Trade/Device Name: Cova™MAX Resorbable Membrane for Guided Tissue and Bone Regeneration
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: August 23, 2011
Received: August 24, 2011

Dear Ms. Centis:

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.

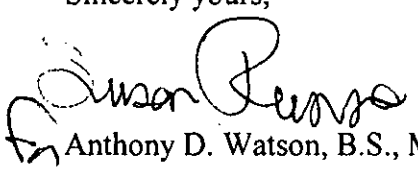
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

K103087

Indications for Use

510(k) Number (if known):

Device Name: Cova™MAX Resorbable Membrane for Guided Tissue and Bone Regeneration

Indications for Use:

Cova™MAX is intended for use in oral surgical procedures as a resorbable membrane material for use in:

-Simultaneous use of GBR-membrane (Guided Bone Regeneration) 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 and removal of retained teeth;
-Guided bone regeneration in dehiscence defects;
-Guided tissue regeneration procedures in periodontal and recession defects.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 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

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

510(k) Number: K103087