K101453

JUL 2 1 2011

510(k) Summary

Date Prepared:	May 19, 2010
Sponsor :	OBI Biologics, Inc. 4620 71st Street, Bldg 79 Lubbock, TX 79424
FDA Establishment Registration #:	N/A (registration after 510(k) submission approval)
Contact Person:	Dustyn Webb Director of Regulatory Affairs 806-796-1923 (phone) 806-796-0059 (fax) dustyn@cytoplast.com (email)
Proprietary Name:	Vitala™
Common Name:	Resorbable Natural Collagen Membrane
Regulatory Classification Name: (Regulation Number) [Product Code]	Bone Grafting Material (872.3930) [NPL]
Device Classification:	Class II (Class II Special Controls Guidance Document: Dental Bone Grafting Material Device)
Predicate Devices:	BIO-GIDE® (K050446) CopiOs™ Pericardium Membrane (K073097) Ossix™ -Plus (K053260)

Device Description

Vitala™ Resorbable Natural Collagen Membrane is a natural collagen membrane sourced from veterinary certified pigs. **Vitala™ Resorbable Natural Collagen Membrane**, minimally manipulated without further cross-linking, is sterilized in a double tray package configuration via E-beam irradiation.

Indications for Use

Vitala™ Resorbable Natural Collagen Membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for:

- Simultaneous use with 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;
- Alveolar ridge preservation consequent to tooth extraction;
- Filling of bone defects after root resection, cystectomy, removal of retained teeth;
- Over the window in lateral window sinus elevation procedures;
- Furcation defects in multi-rooted teeth;
- Treatment of recession defects, together with coronally positioned flap;
- In implants with vertical bone loss due to infection, only with satisfactory debridement and implant surface disinfection;
- Guided bone regeneration in dehiscence defects; and
- Guided tissue regeneration in periodontal defects.

Substantial Equivalence Comparison Chart

Property	Vitala™ Resorbable Natural Collagen Membrane (K101453) OBI Biologics, Inc.	BIO-GIDE® (K050446) Geistlich-Pharma	CopiOs™ Pericardium Membrane (K073097) RTI Biologics, Inc.	Ossix™-Plus (K053260) Colbar Life Science, Ltd.
SIMILAR MODELS/SIZES	13mm x 25mm, 15mm x 20mm, 20mm x 30mm, 30mm x 40mm, 40mm x 50mm	13mm x 25mm, 25mm x 25mm, 40mm x 50mm	15mm x 20mm, 20mm x 30mm, 30mm x 40mm	15mm x 25mm, 25mm x 30mm, 30mm x 40mm
SIMILAR INTENDED USE	**Vitala™ Resorbable Natural Collagen Membrane** is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for: • Simultaneous use with 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; • Alveolar ridge preservation consequent to tooth extraction; • Filling of bone defects after root resection, cystectomy, removal of retained teeth; • Over the window in lateral window sinus elevation procedures; • Furcation defects in multi-rooted teeth; • Treatment of recession defects, together with coronally positioned flap; • In implants with vertical bone loss due to infection, only with satisfactory debridement and implant surface disinfection; • Guided bone regeneration in dehiscence defects; and • Guided tissue regeneration in periodontal defects.	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 in periodontal defects.	This membrane is intended for use in oral surgical procedures as a resorbable material for 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 (GTR) as a 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 intrabony defects around teeth. • For treatment of recession defects, together with coronally positioned flap. • In furcation defects in multi-rooted teeth.
INCORPORATES SAME BASIC DESIGN	Yes	Yes	Yes	Yes
UTILIZES THE SAME OPERATING PRINCIPLE	Cell-occlusive Implantable Resorbable Hemostatic	Cell-occlusive Implantable Resorbable Hemostatic	Cell-occlusive Implantable Resorbable Hemostatic	Cell-occlusive Implantable Resorbable Hemostatic
INCORPORATES SIMILAR MATERIALS	Yes , porcine collagen	Yes , porcine collagen	Yes, bovine collagen	Yes, porcine collagen
STERILIZATION PROCESS	Irradiation	Irradiation	Irradiation	Irradiation
BIOCOMPATIBLE	Yes	Yes	Yes	Yes
NON-PYROGENIC	Yes	Yes	Yes	Yes
SHELF LIFE	TBD (to be determined)	36 Months	60 months	36 months

Basis for Substantial Equivalence

The **Vitala™ Resorbable Natural Collagen Membrane** consists of material (porcine collagen) that is very similar in material composition to the predicate devices, BIO-GIDE® (porcine collagen), CopiOs™ Pericardium Membrane (bovine collagen) and Ossix™-Plus (porcine collagen). Design, function and intended use are substantially equivalent to the corresponding characteristics of the predicate devices. Although minor differences exist in terms of manufacturing processing, medical device packaging, and handling characteristics among **Vitala™ Resorbable Natural Collagen Membrane** and the three predicate devices, these minor differences raise no new issues of safety and efficacy of **Vitala™ Resorbable Natural Collagen Membrane.**

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

Mr. Dustyn Webb
Director of Regulatory Affairs
OBI Biologics, Incorporated
4620 71st Street, Building 79
Lubbock, Texas 79424

JUL 21 2011

Re: K101453
Trade/Device Name: Vitala Resorbable Natural Collagen Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: July 1, 2011
Received: July 13, 2011

Dear Mr. Webb:

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,

Anthony D. Watson

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

Indications for Use

510(k) Number (if known): **K101453**

Device Name: **Vitala™ Resorbable Natural Collagen Membrane**

Indications for Use:

Vitala™ Resorbable Natural Collagen Membrane is intended for use during the process of guided bone regeneration (GBR) and guided tissue regeneration (GTR) as a biodegradable barrier for:

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- Over the window in lateral window sinus elevation procedures;
- Furcation defects in multi-rooted teeth;
- Treatment of recession defects, together with coronally positioned flap;
- In implants with vertical bone loss due to infection, only with satisfactory debridement and implant surface disinfection;
- Guided bone regeneration in dehiscence defects; and
- Guided tissue regeneration in periodontal 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)

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

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