**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: Bone Grafting Material
(Regulation Number) (872.3930)
(Product Code) [NPL]

Device Classification: Class II
(Class II Special Controls Guidance Document: Dental Bone Grafting Material Device)

Predicate Devices: BIO-GIDE® (K050446)  
CopiO™ Pericardium Membrane (K073097)  
Ossix™-Plus (K052360)

**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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Vitala™ Resorbable Natural Collagen Membrane (K101453) ORI Biologics, Inc.</th>
<th>BIO-GIDE® (K050446) Geistlich-Pharma</th>
<th>CopiO™ Pericardium Membrane (K073097) RTI Biologics, Inc.</th>
<th>Ossix™-Plus (K053260) Colbar Life Science, Ltd.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SIMILAR MODELS/SIZES</strong></td>
<td>13mm x 25mm, 15mm x 20mm, 20mm x 30mm, 30mm x 40mm, 40mm x 50mm</td>
<td>13mm x 25mm, 25mm x 25mm, 40mm x 50mm</td>
<td>15mm x 20mm, 20mm x 30mm, 30mm x 40mm</td>
<td>15mm x 25mm, 25mm x 30mm, 30mm x 40mm</td>
</tr>
<tr>
<td><strong>SIMILAR INTENDED USE</strong></td>
<td>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:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Simultaneous use with implants;</td>
<td>• Augmentation around implants placed in immediate extraction sockets;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Augmentation around implants placed in delayed extraction sockets;</td>
<td>• Augmentation around implants placed in delayed extraction sockets;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Localized ridge augmentation for later implantation;</td>
<td>• Localized ridge augmentation for later implantation;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Alveolar ridge reconstruction for prosthetic treatment;</td>
<td>• Alveolar ridge reconstruction for prosthetic treatment;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Alveolar ridge preservation consequent to tooth extraction;</td>
<td>• Filling of bone defects after root resection;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Filling of bone defects after root resection, cystectomy, removal of retained teeth;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Over the window in lateral window sinus elevation procedures;</td>
<td>• Guided bone regeneration in dehiscence defects;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Fissure defects in multi-rooted teeth;</td>
<td>• Guided tissue regeneration in periodontal defects.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Treatment of recession defects, together with coronally positioned flap;</td>
<td>• Augmentation around sockets; localised ridge augmentation and implant insertion;</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• In implants with vertical bone loss due to infection, only with satisfactory debridement and implant surface disinfection;</td>
<td>• Ridge augmentation around implants inserted in delayed extraction sites.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Guided bone regeneration in dehiscence defects; and</td>
<td>• Ridge augmentation around implants in immediate extraction sites,</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Guided tissue regeneration in periodontal defects.</td>
<td>• Alveolar ridge preservation consequent to tooth (teeth) extraction(s);</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>INTEGRATES SAME BASIC DESIGN</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>UTILIZES THE SAME OPERATING PRINCIPLE</strong></td>
<td>Cell-occlusive</td>
<td>Cell-occlusive</td>
<td>Cell-occlusive</td>
<td>Cell-occlusive</td>
</tr>
<tr>
<td></td>
<td>Implantable</td>
<td>Implantable</td>
<td>Implantable</td>
<td>Implantable</td>
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<tr>
<td></td>
<td>Resorbable</td>
<td>Resorbable</td>
<td>Resorbable</td>
<td>Resorbable</td>
</tr>
<tr>
<td></td>
<td>Hemostatic</td>
<td>Hemostatic</td>
<td>Hemostatic</td>
<td>Hemostatic</td>
</tr>
<tr>
<td><strong>INCOUPONATES SIMILAR MATERIALS</strong></td>
<td>Yes, porcine collagen</td>
<td>Yes, bovine collagen</td>
<td>Yes, porcine collagen</td>
<td>Yes, porcine collagen</td>
</tr>
<tr>
<td><strong>STERILIZATION PROCESS</strong></td>
<td>Irradiation</td>
<td>Irradiation</td>
<td>Irradiation</td>
<td>Irradiation</td>
</tr>
<tr>
<td><strong>BIOSINCOMPATIBLE</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>NON-PYROGENIC</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>SHELF LIFE</strong></td>
<td>TBD (to be determined)</td>
<td>36 Months</td>
<td>60 months</td>
<td>36 months</td>
</tr>
</tbody>
</table>

**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), CopiO™ 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.

ORI Biologics, Inc.
Vitala™ Resorbable Natural Collagen Membrane
510(k) Premarket Notification Submission
Mr. Dustyn Webb  
Director of Regulatory Affairs  
OBI Biologics, Incorporated  
4620 71st Street, Building 79  
Lubbock, Texas 79424

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” (21 CFR 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,

[Signature]
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:

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- 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)

[Signature]

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

510(k) Number: **K101453**

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