DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22, 2014

CollaFirm, LLC
Dr. Surendra P. Batra
Founder and Chief Executive Officer
7 Deer Park Drive, Suite M-7
Monmouth Junction, New Jersey 08852

Re: K141721
Trade/Device Name: Bovine Pericardium Patch
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXE, OXB, PAJ
Dated: November 24, 2014
Received: November 25, 2014

Dear Dr. Batra:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Bovine Pericardium Patch

Indications for Use *(Describe)*
Bovine Pericardium Patch is intended for use as an implant for the surgical repair of soft tissue deficiencies, this includes but is not limited to the following:

Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incisions and excision of the lung and bronchus.

Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. Abdominal and thoracic wall repair, muscle flap reinforcement, rectal prolapse excluding rectocele, reconstruction of the pelvic floor excluding transvaginal organ prolapse repair, and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Bovine Pericardium Mesh is provided below.

Device Common Name:	Surgical Mesh
Device Proprietary Name:	Bovine Pericardium Patch
Submitter:	CollaFirm, LLC 7 Deer Park drive, Suite M-7 Monmouth Junction, NJ 08852
Contact:	Surendra P. Batra, Ph. D Founder & CEO, CollaFirm LLC Phone: (732) 823-1051 surendra@collafirm.com
Prepared By:	Stephen P. Rhodes Biologics Consulting Group, Inc.
Date Prepared:	June 25, 2014
Classification Regulation:	21 CFR 878.3300, Class II
Panel:	79 General & Plastic Surgery
Product Code:	FTM, OXE, OXB, PAJ
Predicate Device:	Veritas® Collagen Matrix, Synovis Surgical Innovations K062915

Indication for Use:

Bovine Pericardium Patch is intended for use as an implant for the surgical repair of soft tissue deficiencies, this includes but is not limited to the following:

Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy / pneumectomy, pneumoreduction) and other incisions and excision of the lung and bronchus.

Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding.

Abdominal and thoracic wall repair, muscle flap reinforcement, rectal prolapse excluding rectocele, reconstruction of the pelvic floor excluding transvaginal organ prolapse repair, and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical).

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Device Description:

The Bovine Pericardium Patch is intended for use as an implant to reinforce soft tissue where weakness exists. The Bovine Pericardium Patch is derived from bovine pericardium tissue. The tissue is subjected to decontamination and decellularization processing using non-toxic reagents. The resulting mesh is intended for use as a resorbable implant for soft tissue repair which subsequently remodels and is integrated in the host connective tissue. The Bovine Pericardium Patch is terminally sterilized and is available in sizes ranging from 2cm x10cm to 8cm x16cm.

Performance Data:

Mechanical testing, biocompatibility testing and animal testing were conducted per the recommendations in: *Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance – Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh," dated March 2, 1999.*" The following tests were conducted:

Biocompatibility

- In Vitro Cytotoxicity
- Skin Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Genotoxicity
- Muscle Implantation
- In Vitro Hemolysis
- Pyrogenicity
- Subchronic Systemic Toxicity

Bench/Laboratory Testing

- Tensile Strength
- Suture Retention Strength
- Burst Force
- Tear Resistance
- DNA Residuals
- Collagen Analysis
- Viral Inactivation
- Stability

The biocompatibility testing showed the comparable safety profile of the Bovine Pericardium Patch and the predicate. Bench testing demonstrated that the mechanical properties of the mesh are substantially equivalent for reinforcing soft tissue.

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Substantial Equivalence:

As summarized in Table 1 below, the Bovine Pericardium Patch is substantially equivalent to the predicate device with respect to design, physical shape, characteristics, basic principles of operation and intended use.

Table 1: Device Comparison Table

	Bovine Pericardium Patch	**Veritas® Collagen Matrix**
510(k) Number	TBD	K062915
Submitter	CollaFirm	Synovis Surgical Innovations
Classification Regulation	21 CFR 878.3300, Class II	21 CFR 878.3300, Class II
Product Code	FTM, OXE, OXB, PAJ	FTM, OXE, OXB, PAJ
Indication	Bovine Pericardium Patch is intended for use as an implant for the surgical repair of soft tissue deficiencies, this includes but is not limited to the following: Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy / pneumectomy, pneumoreduction) and other incisions and excision of the lung and bronchus. Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. Abdominal and thoracic wall repair, muscle flap reinforcement, rectal prolapse excluding rectocele, reconstruction of the pelvic floor excluding transvaginal organ prolapse repair, and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical).	Veritas® Collagen Matrix is intended for use as an implant for the surgical repair of soft tissue deficiencies, this includes but is not limited to the following: Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy / pneumectomy, pneumoreduction) and other incisions and excision of the lung and bronchus. Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding. Abdominal and thoracic wall repair, muscle flap reinforcement, rectal prolapse excluding rectocele, reconstruction of the pelvic floor excluding transvaginal organ prolapse repair, and repair of hernias (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical). Veritas® Collagen Matrix minimizes tissue attachment to the device in case of direct contact

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	Bovine Pericardium Patch	**Veritas® Collagen Matrix**
		with viscera.
Rx/OTC	Rx	Rx
Physical Shape	Rectangular Patch	Rectangular Patch
Available Sizes	Various sizes ranging from 2x8cm to 12x25cm	Various sizes ranging from 2x8cm to 12x25cm
Product Description	Type I Bovine Collagen	Type I Bovine Collagen
Animal Tissue	Bovine Pericardium	Bovine Pericardium
Sterile	Yes (E-Beam)	Yes (E-Beam)
Pore Size (SEM)	1-3 µm	1-4 µm
Average Device Thickness	0.55mm	0.67mm
Storage	20-25°C	20-25°C
Handling characteristics	Flexible	Flexible

Conclusion

Based on the indications for use, technological characteristics and performance test results, the Bovine Pericardium Patch is substantially equivalent to the predicate.