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

October 20, 2016

Colorado Therapeutics LLC
Mr. William Jackson
Vice President Regulatory, Clinical, And Compliance
2150 West 6th Avenue, Suite L
Broomfield, Colorado 80020

Re: K160181
Trade/Device Name: Colorado Therapeutics Xenograft Implant
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: FTM, OXK
Dated: September 19, 2016
Received: September 20, 2016

Dear Mr. Jackson:

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" (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 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,

David Krause -S

for 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)*
K160181

Device Name
Colorado Therapeutics Xenograft Implant

Indications for Use *(Describe)*
Colorado Therapeutics Xenograft Implant is intended to be used for implantation to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes.

It is supplied sterile.

It is intended for one-time use.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

1. SUBMITTER

Name and Address: of Submitter	Colorado Therapeutics LLC 2150 West 6th Avenue Suite L Broomfield, Colorado 80020 303.469.9459
Contacts:	William (Bill) Jackson Vice President Regulatory, Clinical, and Compliance
Prepared by and Date:	William (Bill) Jackson, October 18, 2016

2. DEVICE

Name of Device:	Colorado Therapeutics Xenograft Implant
Common or Usual Name:	Surgical Mesh
Classification Name:	Surgical Mesh (21 C.F.R. §878.3300)
Device Class:	Class II
Product Code:	FTM and OXK

3. PREDICATE DEVICES

Predicate Device:	Permacol™ Surgical Implant, Covidien (K120605) This product has not been subject to a design-related recall.
Predicate Device:	Surgisis® Biodesign® Hernia Graft, Cook Biotech (K980431) This product has not been subject to a design-related recall.
Reference Devices:	No reference devices are stated in this traditional 510(k) Premarket Notification.

4. DEVICE DESCRIPTION

Colorado Therapeutics Xenograft Implant is a sterile implant consisting of porcine pericardium. It is glutaraldehyde cross-linked, sterilized by ethylene oxide (EO) and packaged dry with no rehydration required. The Colorado Therapeutics proprietary process produces a uniquely thin and dry xenograft implant that provides the suitable strength, and biocompatibility for a soft tissue repair implant.

5. INDICATIONS FOR USE

Colorado Therapeutics Xenograft Implant is intended to be used for implantation to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes.

It is supplied sterile.

It is intended for one-time use.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The Colorado Therapeutics Xenograft Implant (XI) is an implantable, surgical implant that is derived from Porcine Pericardium. It is comprised primarily of Collagen Type I, Type II, Type III, and Type IV. It functions as a xenograft implant to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes, as do the predicates.

Non Clinical Tests Submitted: Colorado Therapeutics LLC followed the Guidance for the Preparation of a Premarket Notification for a Surgical Mesh, issued March 2, 1999, which is attached as Appendix 1.

Biocompatibility covered testing for cytotoxicity, sensitization, irritation, systemic toxicity, genotoxicity, implantation, hemolysis, subchronic toxicity, and chronic toxicity. Both predicates underwent the same testing.

Product characterization included data for glutaraldehyde residuals, heavy metals (final and unprocessed porcine pericardium), volatile organic compounds, collagen typing, collagenase degradation, pore structure, DNA concentration, mesh thickness, mesh weave characteristics, mesh density, tensile strength, device stiffness, suture pullout strength, and tear resistance.

The resorption profile of the XI material (glutaraldehyde crosslinked porcine pericardium) was characterized through exposure to physiological conditions *in vivo* using a small animal model: rabbits with inlay, bridged hernia repair. Histopathological matrix degeneration scores demonstrated equivalence to our predicate, K120605 Permacol. At 90 days, in the rabbit the Xenograft Implant and our predicate, K120605 Permacol, were both observed and had equivalent inflammatory response score of mild and moderate. In addition, the XI material was challenged with an *in vitro* accelerated degradation environment-collagenase solution. In the in vitro collagenase evaluation equivalent score of degradation for the XI material and K120605 Permacol device were observed. Thickness comparisons were made via measurements of the histological images. Mechanical strength was determined through uniaxial testing. Overall, both the animal and *in vitr*o study findings are substantiated with predicate device or published literature.

Bench testing demonstrated the mechanical properties of the Xenograft Implant and the predicates are substantially equivalent.

Clinical Tests Submitted: Not Applicable; no clinical tests are submitted for this 510(k).

Conclusion: The Colorado Therapeutics Xenograft Implant was found to be substantially equivalent to the predicate devices in technological characteristics, indications for use/intended use, biocompatibility, and product characterizations.