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

November 15, 2016

Amorchem Holdings, Inc.
% Robert Poggie, Ph.D.
President, BioVera, Inc.
65 Promenade Saint Louis
Notre Dame De Lile Perrot,
Québec, J7V7P2
Canada

Re: K160791
Trade/Device Name: Amorchem Porous Titanium Fixation Device
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTY
Dated: October 12, 2016
Received: October 13, 2016

Dear Dr. Poggie:

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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic 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)*
K160791

Device Name
AmorChem Porous Titanium Fixation Device

Indications for Use *(Describe)*
The AmorChem 3.8 mm Headless Porous Titanium Compression Screw is used for fixation of bone fractures, bone reconstruction, and fixation of osteotomies.

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.

510(k) SUMMARY

AmorChem Porous Titanium Fixation Device

In accordance with 21 CFR 807.92, the following information is a summary of safety and effectiveness for the AmorChem Porous Titanium Fixation Device.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-De-L'Ile-Perrot, Québec, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Title:	President
Phone Number:	(514) 901-0796; (514) 349-7226
Fax Number:	(514) 901-0796
Date of Submission:	November 14, 2016

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	AmorChem Holdings, Inc.
Manufacturer Address:	1, Westmont Square Montreal, Quebec, H3Z 2P9 Canada
Registration Number:	Not registered
Contact Name:	Kevin McBride, MsC, PhD
Title:	Vice President, Research
Device Trade Name:	AmorChem Porous Titanium Fixation Device
Device Common Name:	Metallic bone screw
Classification Name:	Smooth or threaded metallic bone fixation fastener
Classification Code:	HWC, HTY – Class II
Classification Panel:	Orthopedic
Regulation Number:	21 CFR section 888.3040

C1. PREDICATE DEVICES

K143618 **Primary predicate**	Zimmer Kirschner Wires and Steinmann pins
K930834 **Additional predicate**	Acutract compression screw
K102528 **Additional predicate**	N-Force Fixation System

C2. REFERENCE DEVICES

K071616	The ARC Surgical BIOTRAK Pin System
K041189	The Arthrex TrimIt family
K140879	Smith & Nephew BIOSURE HEALICOIL PK Interference Screw

D. DEVICE DESCRIPTION

The AmorChem Porous Titanium Fixation Device is a 3.8mm, 15mm long variable pitch, fully threaded, cannulated, and headless compression screw. The AmorChem screw is designed to be inserted into a pre-drilled hole that can be guided with a standard k-wire or Allen-drive k-wire. The headless design is intended to be seated flush with the surface of bone. The device is 40% titanium with interconnected porosity. The AmorChem device is provided clean, not sterile, and is single-use only.

Materials: Porous titanium.

E. INDICATIONS FOR USE

The AmorChem 3.8 mm Headless Porous Titanium Compression Screw is used for fixation of bone fractures, bone reconstruction, and fixation of osteotomies.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject AmorChem Porous Titanium Fixation Device is a 3.8mm, 15mm long variable pitch, fully threaded, cannulated, and headless compression screw made entirely of 40% porous titanium. The characteristics of variable pitch thread, tapered design, through-cannulation, and size of the AmorChem device are the same as the predicate Acumed device. The main technological differences are the porous titanium and hexagonal drive along the entire length of the AmorChem device; the Acumed device is fabricated from titanium alloy with the hex drive confined to the proximal end of the screw.

The porous titanium material is intended to allow biological fixation. In vitro testing per ASTM F543, 3-point static and fatigue bend testing, ISO 10993 evaluation of cytotoxicity, chemistry and associated risk analysis, and evaluation of biological fixation and biocompatibility in ovine models of gap healing, osteonecrosis, and cortical bone showed the AmorChem device to be substantially equivalent to the predicate devices.

G. PERFORMANCE DATA

Characterization of the AmorChem Porous Titanium Fixation Device was performed per in-vitro and in-vivo laboratory testing, and assessment of biocompatibility per the chemical characterization and risk analysis route described in ISO 10993-1 and recommended by FDA in pre-submission Q150543. More specifically:

- Biomechanical evaluation of the AmorChem device was evaluated for torsional properties, torque-in, torque-out, and holding strength per consensus testing standards ASTM F 543 and F 2502. The results of these tests showed the AmorChem device to

possess similar torque-in and -out properties as the Acumed predicate device, superior holding power to the k-wire primary-predicate device.

- Strength of the subject AmorChem device and the k-wire primary-predicate device was evaluated in static and fatigue 3-point bend testing using ASTM F1264 and ASTM F1541 as guides. The AmorChem device was found to be substantially stronger in 3-point bending than the primary-predicate k-wire device.
- Biocompatibility was assessed by quantifying the presence of leachables / extractables and toxicological risk assessment by NAMSA per ISO 10993-1, -5, -6, -12, -17, and -18, ISO 14971: 2012, FDA G-95-1 Bluebook guidance, and USP Physiochemical Tests. The chemical analysis showed the levels of residual compounds to be below detectable levels, or presenting no risk of safety. ISO 10993-6 evaluation of local tissue effects by AccelLAB of the subject device showed no adverse effects. The porous titanium material and subject device were found to be biocompatible for permanent implantation.
- Ovine modeling of biological fixation and biocompatibility at 6- and 12-weeks post-op showed the subject AmorChem Porous Titanium Fixation Device to be biologically fixed via the interconnected porous structure and cannula of the device.

The results of the performance testing indicate the AmorChem Porous Titanium Fixation Device to be substantially equivalent to the identified predicate devices.

H. CONCLUSION

The AmorChem Porous Titanium Fixation Device is substantially equivalent to the predicate devices cited in this 510(k) application.