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

July 29, 2016

Miami Device Solutions, LLC
% Robert Poggie, Ph.D.
President
Biovera Incorporated
65 Promenade Saint Louis
Notre-dame-de-l'ile-perrot,
QC J7V7P2
Canada

Re: K161058
Trade/Device Name: Cannulated Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HRS
Dated: June 13, 2016
Received: June 15, 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,

Vincent J. Devlin -S

for
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)*
K161058

Device Name
Cannulated Screw

Indications for Use *(Describe)*
The Cannulated Screw for the Proximal Humerus Plating System is indicated for internal fixation of fractures of the proximal humerus.

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.

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510(k) SUMMARY

Line Extension - Cannulated Screw for the Proximal Humerus Plating System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following is a summary of safety and effectiveness of the *Cannulated Screw*.

A. SUBMITTERS INFORMATION, DEVICE IDENTIFICATION, AND MANUFACTURER

Name:	Miami Device Solutions, LLC
Address:	7620 NW 25th Street, Unit 3, Miami, FL 33122, USA
Registration Number:	3009222247
Contact Name:	Markku Biedermann
Title:	President
Device Trade Name:	Cannulated Screw
Device Common Name:	Bone screw
Classification Name:	Plate, fixation, bone; and Screw, fixation, bone
Classification Codes:	HWC and HRS – Class II
Classification Panel:	Orthopedic
Regulation Number:	21 CFR section 888.3040 and 888.3030

B. CORRESPONDENT INFORMATION

Name:	BioVera, Inc.
Address:	65 Promenade Saint-Louis, Notre-Dame-De-L'Ile-Perrot, Québec, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796; (973) 738-6097
Fax Number:	(514) 901-0796
Date of Submission:	July 28, 2016

C.1. PREDICATE DEVICES

K141493	Miami Device Solutions, LLC Proximal Humerus Plating System
K041965	Arthrex Inc., Arthrex Humeral Fracture Plates & Screws
K040593, K042598, K043227, K043560, K050121, K051098	Zimmer, Inc. Proximal Humeral Plating System

C.2. REFERENCE DEVICES

K151418	Paragon 28, Inc.; the Monster Screw System: Instrument Reprocessing Instructions for Reusable Instruments

D. DEVICE DESCRIPTION

The Miami Device Solutions (MDS) Cannulated Screw is a cannulated bone screw intended for use with the MDS Proximal Humerus Plating System cleared in K141493. The MDS cannulated bone screw is 3.5 mm in diameter, 30 to 60 mm in length in 3 mm increments, fully cannulated and threaded, and can interface with MDS Proximal Humerus Plates and Locking Caps cleared in K141493. The MDS device is supplied not sterile and is single-use only.

Materials: Ti-6Al-4V ELI alloy conforming to ASTM F136.

E. INTENDED USE

The Proximal Humerus Plating System is indicated for internal fixation of fractures of the proximal humerus.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject device is a titanium alloy, fully threaded, polyaxial, cannulated bone screw for use with the MDS Proximal Humerus Plating System. It is available in one diameter, 3.5 mm, and length options of 30 to 60 mm in 3 mm increments, and can be used with MDS plates and locking caps cleared in K141493. The subject Cannulated Screw is a line extension to the cleared MDS Proximal Humerus Plating System for the purpose of providing surgeons the option to guide the screw with a K-wire.

The material (Ti-6Al-4V ELI), indications for use, diameter, drive-interface detail, and polyaxial cone of angulation of the subject Cannulated Screw are identical to MDS non-cannulated screws cleared in K141493 for the MDS Proximal Humerus Plating System. Performance testing of the MDS and Zimmer devices per ASTM F543 showed the subject cannulated screw to possess similar strength and performance characteristics as the predicate Zimmer cannulated screw, and the Arthrex predicate device (K041965). The MDS Cannulated Screw was determined to be substantially equivalent to the Zimmer and Arthrex predicate devices.

G. PERFORMANCE DATA

Characterization of the subject MDS Cannulated Screw and Predicate Zimmer Cannulated Screw was performed per consensus standard ASTM F543. More specifically, the subject MDS and predicate Zimmer cannulated screws were evaluated for torsional strength, torque-in, torque-out, and axial pull out strength. The results of these tests showed the MDS device to possess similar performance properties as the Zimmer predicate device, and the Arthrex predicate device (K041965), and therefore do not raise new questions of safety when used per the products labeling.

The results of the performance testing per ASTM F543 indicate the MDS Cannulated Screw to be substantially equivalent to the predicate Zimmer cannulated screw and the predicate Arthrex screw, and to be safe when used per the products labeling and intended use.

H. CONCLUSION

The Miami Device Solutions Cannulated Screw is substantially equivalent to the predicate devices cited in this 510(k) application.