September 18, 2018

Biogennix, LLC
℅ Daniel Johnson
Regulatory Engineer
JALEX Medical, LLC.
30311 Clemens Rd. Suite 5D
Westlake, Ohio 44145

Re: K181337
Trade/Device Name: Sypher Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: August 21, 2018
Received: August 22, 2018

Dear Mr. Johnson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Melissa Hall -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181337

Device Name
Sypher Spacer System

Indications for Use *(Describe)*

The Sypher Spacer System is a standalone intervertebral body fusion system for use in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use with autogenous and/or allogenic bone graft (composed of cancellous and/or corticocancellous bone) at one or two contiguous levels of the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Supplemental fixation is required whenever fewer than 3 bone screws are utilized.

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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K181337
510(k) Summary

Submitted By:	Biogennix, LLC 18007 Sky Park Circle, Suite F Irvine, CA 92614
Date:	08/21/2018
Contact Person:	Daniel Johnson, Regulatory Engineer
Contact Telephone:	(440) 541-0060
Contact Fax:	(440) 933-7839

Device Trade Name:	Sypher Spacer System
Device Common Name:	Intervertebral Fusion Device
Device Classification Name:	Intervertebral Fusion Device With Bone Graft, Lumbar Intervertebral Fusion Device With Integrated Fixation, Lumbar
Regulation Number:	21 CFR 888.3080
Device Classification:	Class II
Product Code:	MAX, OVD
Primary Predicate:	Biogennix Sypher Spacer System (K141798) The predicate device has never been subjected to a recall
Reference Predicates:	Zimmer Biomet Solitaire (K081395, K081501) Zimmer Biomet ROI-A® ALIF Cage System (K153495)

Device Description:

The Sypher Spacer System is a standalone intervertebral body fusion system intended for the lumbar spine. The Sypher Spacer System implants include cylinder shaped blocks manufactured from PEEK-OPTIMA™ LT1 conforming to ASTM F2026, tantalum markers conforming to ASTM F560, titanium alloy self-tapping, self-drilling bone screws conforming to ASTM F136, and titanium alloy cage lock assemblies conforming to ASTM F136.

The implants are available in a variety of footprints, heights, and lordotic angles. The device features a hollow center to accommodate autogenous and/or allogenic bone graft (composed of cancellous and/or corticocancellous bone). The implants have integrated anterior screw holes to allow for medial placement of screws, and a titanium alloy cage lock assembly for securing the screws in place. The superior and inferior surfaces of the implant have a pattern of teeth to prevent movement.

Indications For Use:

The Sypher Spacer System is a standalone intervertebral body fusion system for use in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use with autogenous and/or allogenic bone graft (composed of cancellous and/or corticocancellous bone) at one or two contiguous levels of the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Supplemental fixation is required whenever fewer than 3 bone screws are utilized.

Summary of Technological Characteristics:

The Sypher Spacer System and the predicates have similar intended use and fundamental scientific technology. All devices compare similarly in:

- Design features
- Intended use
- Materials
- Dimensions
- Function

Mechanical Testing:

Substantial Equivalence is supported by the results of mechanical testing and Finite Element Analysis (FEA). The mechanical testing performed includes static compression per ASTM F2077, static shear compression per ASTM F2077, and expulsion testing per ASTM Draft Standard F-04.25.02.02.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate devices, the subject device has demonstrated substantial equivalence.