February 12, 2018

Zimmer Biomet Spine Inc.
Ms. Megan Fessenden
Regulatory Affairs, Senior Specialist
10225 Westmoor Drive
Westminster, Colorado 80021

Re: K171495
Trade/Device Name: Zyston Strut Open Titanium Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: January 9, 2018
Received: January 11, 2018

Dear Ms. Fessenden:

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.

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.

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,

Katherine D. Kavlock -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)*

K171495

Device Name
Zyston Strut Open Titanium Spacer System

Indications for Use *(Describe)*

When used as a lumbar intervertebral body fusion device, the Zyston Strut Open Titanium Interbody Spacer System is intended for spinal fusion procedures to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Zyston Strut Open Titanium Interbody Spacer System is to be implanted via a posterior approach and is to be combined with supplemental fixation. The titanium fusion devices are not indicated for vertebral body replacement.

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.

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ZIMMER BIOMET

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92.

Preparation Date	January 31, 2018
Applicant/Sponsor	Zimmer Biomet Spine Inc 10225 Westmoor Dr. Westminster, CO 80021
Contact Person	Megan Fessenden Regulatory Affairs, Senior Specialist Phone: 303-465-8994 Fax: 303-501-8444
Trade Name	Zyston Strut Open Titanium Spacer System
Common Name	Intervertebral Body Fusion Device, Lumbar
Device Class	Class II
Classification Name	Intervertebral fusion device with bone graft, lumbar
Product Code	MAX
Device Panel – Regulation No.	Orthopedic – 21 CFR 888.3080
Primary Predicate	K143258 - 4Web Spine Truss System (STS)
Additional Predicates	K162262 – Stryker Tritnaium PL Cage, K153695 – Biomet Spine Fusion System

Device Description & Technological Characteristics:

The Zyston Strut Open Titanium Spacer System implants are intervertebral body fusion devices consisting of a rectangular or semi-rectangular shape and various heights and footprints. The devices have an open central area to accommodate autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The implants are available in a variety of sizes and configurations to approximate anatomical variation in different vertebral levels and/or patient anatomy. The implants are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F2924. The Zyston Strut Open Titanium Spacer System implants incorporate lordotic angles of 0 and 10 degrees. The implants are available in 7 to 16mm heights, 10 and 11mm widths, and 21 to 38mm lengths depending on the implant configuration. The Zyston Strut Open Titanium Spacer System implants are intended to be provided sterile.

Intended Use / Indications for Use:

When used as a lumbar intervertebral body fusion device, the Zyston Strut Open Titanium

Interbody Spacer System is intended for spinal fusion procedures to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Zyston Strut Open Titanium Interbody Spacer System is to be implanted via a posterior approach and is to be combined with supplemental fixation. The titanium fusion devices are not indicated for vertebral body replacement.

Summary of Technologies:

The technological characteristics of the subject Zyston Strut Open Titanium Spacer System components remain the same as, or similar to, the predicate devices in regards to intended use, indications for use, design, materials, fundamental technology, and operational principles.

Performance Data:

Mechanical testing was conducted in accordance with FDA's Guidance for Industry and FDA Staff – Spinal System 510(k)s dated May 3, 2004 and Class II Special Controls Guidance Document: Intervertebral Body Fusion Device dated June 12, 2007. Performance testing was performed to demonstrate substantial equivalence to the predicate device(s). Performance testing included tests per ASTM F2077 (static and dynamic axial compression, static and dynamic shear compression, and static torsion) and ASTM F2267 (subsidence). Bacterial endotoxin testing (LAL) as specified in ANSI/ AAMI ST72:2011 is used for pyrogenicity testing to achieve the Endotoxin limit of <20EU/device. In all instances, the subject device met or exceeded predicate device performance, functioned as intended and, therefore, demonstrated substantial equivalence to the predicate device(s).

Substantial Equivalence:

The Zyston Strut Open Titanium Spacer System implants have the same intended use, indications, technological characteristics, and principles of operation as the previously cleared primary predicate, 4Web Spine Truss (STS) (K143258), and the previously cleared other predicates: Stryker Triantium PL Cage (K162262) and Biomet Spine Fusion System (K153695). The subject Zyston Strut components do not raise any new issues of safety or effectiveness compared to predicate device(s). Performance data presented also demonstrated comparable properties to the previously cleared devices.

Conclusion:

The Zyston Strut Open Titanium Spacer System is substantially equivalent to the predicate systems as a spinal fusion device in regards to intended use, indications for use, fundamental technology including design, materials, sterility, and operational principles. Furthermore, mechanical testing and other supporting information sufficiently demonstrate the substantial equivalence of the subject components to the Zyston Strut Open Titanium Spacer System to the predicate system. Based on this information, the subject device does not raise any new issues regarding the safety or efficacy when compared to its predicates.