December 20, 2019

Medos International SARL
% Karin McDonough
Regulatory Affairs Specialist
DePuy Synthes Spine
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K190284
Trade/Device Name: Bengal® Stackable Cage System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PLR, MQP
Dated: November 19, 2019
Received: November 20, 2019

Dear Karin McDonough:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent L. Showalter, PhD
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K190284

Device Name
Bengal® Stackable Cage System

Indications for Use *(Describe)*
The Bengal® Stackable Cage System is indicated for use in the thoracolumbar spine (i.e. T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Bengal® Stackable Cage System is also indicated for treating fractures of the thoracic and lumbar spine. The Bengal® Stackable Cage System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The Bengal® Stackable Cage System is intended for use with supplemental internal fixation.

The Bengal® Stackable Cage System is also indicated for use in the cervical spine (C3-C7 vertebral bodies for the standard and large VBR implant) in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral body due to tumor, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues. The Bengal® Stackable Cage System for use in the cervical spine is designed to restore the integrity of spinal column even in the absence of fusion for a limited time period, in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with the surgeon's bone graft material of choice.
The Bengal® Stackable Cage System is intended for use with supplemental internal fixation. When used at more than two levels in the cervical spine, supplemental fixation should include posterior fixation that has been cleared by FDA.

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."

510(K) SUMMARY

A. Submitter Information

510(k) Sponsor: DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767

Contact Person: Karin McDonough
DePuy Synthes Spine
325 Paramount Drive
Raynham, MA 02767
Telephone: (508) 977-3851
Fax: (508) 828-3797
Email: kmcdono3@its.jnj.com

B. Date Prepared

December 20, 2019

C. Subject Device Name

Trade/Proprietary Names: Bengal® Stackable Cage System
Common/Usual Names: Spinal Intervertebral Body Fixation Orthosis
Classification Names: Class II
Spinal Intervertebral Body Fixation Orthosis
Per 21 CFR 888.3060
Product codes: **PLR, MQP**

D. Primary Predicate Device Name

Trade/Proprietary Names: Modulift Vertebral Body Replacement (VBR) System (K172032)
Common/Usual Names: Spinal Vertebral Body Replacement Device Cervical
Classification Names: Class II
Spinal Intervertebral Body Fixation Orthosis
21 CFR 888.3060
Product codes: **PLR**

E. Additional Predicate Device Name

Trade/Proprietary Names:	Bengal Stackable Cage System (K073649, K140759)
Common/Usual Names:	Spinal Intervertebral Body Fixation Orthosis
Classification Names:	Class II Intervertebral Fusion Device with Bone Graft, Lumbar Per 21 CFR 888.3080
Product codes:	**MAX, MQP**

F. Submission Purpose

The purpose of this submission is to seek clearance to expand the indication for use for Bengal Stackable Cage System to include the cervical spine (C3-C7).

G. Device Description

The Bengal Stackable Cage System is a VBR Spinal System designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period, as well as for treating fractures of the thoracic and lumbar spine.
The structure of the polymer/carbon-fiber composite implants has been shown to support anticipated loads with a modulus of elasticity approximating that of cortical bone. The implants have ridges or teeth in both the anterior-posterior and medial-lateral directions, which resist rotation and migration. The polymer/carbon-fiber composite implants have cavities to accept packing of bone graft.

H. Indications for Use

The Bengal® Stackable Cage System is indicated for use in the thoracolumbar spine (i.e. T1-L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.
The Bengal® Stackable Cage System is also indicated for treating fractures of the thoracic and lumbar spine.
The Bengal® Stackable Cage System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.
The Bengal® Stackable Cage System is intended for use with supplemental internal fixation.

The Bengal® Stackable Cage System is also indicated for use in the cervical spine (C3-C7 vertebral bodies for the standard and large VBR implant) in skeletally mature patients for partial or total replacement of a diseased, collapsed, damaged, or unstable vertebral

body due to tumor, trauma (i.e. fracture), or for reconstruction following corpectomy performed to achieve decompression of the spinal cord and neural tissues. The Bengal® Stackable Cage System for use in the cervical spine is designed to restore the integrity of spinal column even in the absence of fusion for a limited time period, in patients with advanced stage tumors involving the cervical, thoracic, and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion, with the surgeon's bone graft material of choice.
The Bengal® Stackable Cage System is intended for use with supplemental internal fixation. When used at more than two levels in the cervical spine, supplemental fixation should include posterior fixation that has been cleared by FDA.

I. Summary of Similarities and Differences in Technological Characteristics, Performance, and Intended Use

The technological characteristics of the subject Bengal Stackable Cage System remain unchanged from their currently marketed predicate version in their design, material, performance, and intended use.

J. Materials

The materials of the subject implants remain unchanged from that of the previously cleared implants.

The Bengal Stackable Cage System implants are made of a polymer/carbon-fiber composite. The polymer/carbon-fiber composite is made from PEEK Optima LT1DA30 which complies with ASTM F2026-12, USP Class VI and ISO 10993-1. The Bengal cages have a tantalum ball per ASTM-F560 and a nut component made from titanium alloy, same as the screws, Ti-6Al-4V per ASTM F136.

The accessories are all class I instruments made from stainless steel, silicone and polypropylene (or polyprolylux) a material that complies with ASTM D4101 for extruded polypropylene.

K. Performance Data

A literature analysis of published clinical data is provided to support the modified indication for use. The clinical outcomes demonstrate that interbody fusion devices similar to the subject devices are as safe and effective as the primary predicate devices and the additional predicate devices for the modification indication for use. No additional testing was required as the technological characteristics are consistent and or similar with those of the primary predicate device and the additional predicate device.

L. Conclusion

The substantial equivalence justification provided in this submission demonstrates that the subject device is equivalent to the safety and effectiveness of the predicate devices. The intended use and technological characteristics are consistent and/or similar with those of both the primary predicate device and the additional predicate devices.