November 16, 2021

Southern Spine LLC
℅ Julie Stephens
President/Consultant
Regulatory Resources Group, Inc.
111 Laurel Ridge Dr
Alpharetta, Georgia 30004

Re: K211845
Trade/Device Name: Deploy™ Expandable Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 21, 2021
Received: July 22, 2021

Dear Ms. Stephens:

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 Showalter, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211845

Device Name
Deploy™ Expandable Interbody System

Indications for Use *(Describe)*
The Deploy™ Expandable Interbody System implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative disc disease (DDD) at one level or two contiguous levels of the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients should be skeletally mature and have at least six months of non-operative treatment prior to being treated with this system. Additionally, the Deploy™ implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. Deploy™ implants are intended to be used with supplemental spinal fixation systems that are cleared for use in the lumbosacral spine.

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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Southern Spine LLC
Traditional 510(k): K211845 - Deploy™ Expandable Interbody System

510(k) Summary

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

Submitted By: Southern Spine LLC
487 Cherry Street – Third Street Tower
Macon, GA 31201
Phone: (478) 745-0000

Contact Person: Julie Stephens, President/Consultant
Regulatory Resources Group, Inc. - Phone: (678) 513-0693

Date Submitted: November 12, 2021

Device Name and Classification:

Trade/Proprietary Name:	Deploy™ Expandable Interbody System
Common Name:	Intervertebral body fusion device
Regulation Number:	21 CFR 888.3080
Regulation Name:	Intervertebral fusion device with bone graft, lumbar
Class:	II
Product Code:	MAX

Legally Marketed Predicate Devices:

Primary Predicate: Amendia Interbody Fusion Devices [Zeus] - 510(k) # K151322
Additional Predicate: MOJAVE Expandable Interbody System - 510(k) # K163364 and K171097
Additional Predicate: Synthes OPAL Spacer/Cage - 510(k) # K072791
None of the predicates have been subject to a design-related recall.

Device Description:

The Deploy™ Expandable Interbody System is comprised of the interbody implant cages, surgical instruments which include trial instruments to aid in the selection of the appropriate implant size for the patient's anatomy, and sterilization trays. The implants are manufactured from titanium alloy Ti-6Al-4V (ASTM F136, ASTM F3001) and are offered with various heights and shapes for different patient anatomy. Each implant is designed to be inserted and then rotate in-situ, providing immediate fixation and the arm deployed for the graft containment area. Ridges on the superior and inferior surfaces of the titanium implants contact the endplates to resist expulsion forces. The implants are designed to be used in conjunction with supplemental spinal fixation instrumentation. The surgical instruments are manufactured from stainless steel (ASTM F899, ISO 7153-1). The implants and surgical instruments are provided non-sterile and require sterilization prior to use within sterilization trays following validated sterilization parameters as provided within the Instructions for Use.

Indications for Use:

The Deploy™ Expandable Interbody System implants are intervertebral body fusion devices indicated for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when used as an adjunct to fusion in patients with degenerative

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510(k) Summary

disc disease (DDD) at one level or two contiguous levels of the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. These patients should be skeletally mature and have at least six months of non-operative treatment prior to being treated with this system. Additionally, the Deploy™ implants can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. Deploy™ implants are intended to be used with supplemental spinal fixation systems that are cleared for use in the lumbosacral spine.

Technological Characteristics:

The Deploy™ Expandable Interbody System and the predicate devices have the same principles of operation as interbody fusion devices in patients at one level or two contiguous levels from L2 to S1. The Deploy™ Expandable Interbody System have the same or similar technological characteristics as its predicate devices through comparison of characteristics including design, intended use, material composition, and function. The proposed implants are classified as permanent implants (more than 30 days), single patient use only, and have validated instructions for cleaning and sterilization.

Summary of Testing:

The biocompatibility risk assessment was completed as directed by FDA guidance under ISO 10993-1 and Parts 5 biocompatibility requirements. Cytotoxicity testing was completed to demonstrate and support justification that the known biocompatible materials, Titanium Alloy (Ti6Al4V ELI) per ASTM F136 and ASTM 3001 standards, maintained compliance through manufacturing processes and cleaning and sterilization instructions validated for the final implants and instruments. The Deploy™ Expandable Interbody System was tested in static axial compression (ASTM F2077), static compressive shear (ASTM F2077), dynamic axial compression (ASTM F2077), dynamic compressive shear (ASTM F2077), static subsidence (ASTM F2267), and wear debris testing (ASTM F1877).

Substantial Equivalence Conclusions:

Deploy™ Expandable Interbody System was shown to be substantially equivalent to predicate systems in terms of indications for use, design, function, material composition, range of sizes, and mechanical performance.