February 26, 2026

Implanet
℅ Jen McBride
Regulatory Consultant
MRC Global, LLC
9160 Hwy 64, Suite 12
P.O . Box 330
Lakeland, Tennessee 38002

Re: K254017
Trade/Device Name: SWINGO-3D Lumbar Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 12, 2025
Received: December 15, 2025

Dear Jen McBride:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254017

Device Name
SWINGO-3D Lumbar Cage System

Indications for Use *(Describe)*
The SWINGO-3D Lumbar Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine, at one or two contiguous levels, from L2 to S1 whose condition requires use of interbody fusion combined with supplemental fixation.
These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.
Patients should have had six months of non-operative treatment prior to surgery.

The SWINGO-3D Lumbar Cage System is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/ or corticocancellous bone graft when the subject device is used as an adjunct to fusion. When used for these indications, the SWINGO-3D Cage System is intended for use with supplemental fixation systems cleared for use in the lumbar 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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510(k) Summary
SWINGO-3D Lumbar Cage System
February 17, 2026

Company: Implanet
Technopole Bordeaux Montesquieu
Allee Francois Magendie
Martillac Nouvelle-Aquitaine, FR 33650

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Trade Name: SWINGO-3D Lumbar Cage System

Common Name: Intervertebral Fusion Device With Bone Graft, Lumbar

Classification: Class II

Regulation: 21 CFR 888.3080

Panel: Orthopedic

Product Code: MAX

Device Description:

The SWINGO-3D Lumbar Cage System consists of three different models of additively manufactured lumbar interbody fusion devices—SWINGO-P-3D (PLIF), SWINGO-T-3D (TLIF), and SWINGO-L-3D (LLIF) – that are intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. These devices consist of additively manufactured titanium alloy (per ASTM F3001) cages of various heights and footprints, which can be inserted between two lumbar to give support and correction during interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autograft and/or allogenic bone graft material. The subject additively manufactured implants are provided sterile via gamma irradiation.

The subject devices are modifications to the nearly-identical devices cleared by Shanghai Sanyou in the predicate submission (K230872). Shanghai Sanyou and Implanet have entered into an agreement in which Implanet will be the legal manufacturer of the subject devices and Shanghai Sanyou will be the contract manufacturer. Under the terms of this agreement, Implanet will maintain the quality system and handle all complaints related to the devices in this submission.

Previously cleared (K163422 and K211689) associated device specific and universal instruments are available to facilitate the implantation of interbody devices. All instruments are manufactured from instrument-grade stainless steel that conforms to ASTM F899. No new instruments are being added.

Indications for Use:

The **SWINGO-3D Lumbar Cage System** is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine, at one or two contiguous levels, from L2 to S1 whose condition requires use of interbody fusion combined with supplemental fixation.

These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.
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The **SWINGO-3D Lumbar Cage System** is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/ or corticocancellous bone graft when the subject device is used as an adjunct to fusion. When used for these indications, the SWINGO-3D Cage System is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Substantial Equivalence:

The subject SWINGO-3D Lumbar Cage System is substantially equivalent to the following predicate devices:

Primary Predicate:

- Shanghai Sanyou Metal Additive Manufacturing Interbody Fusion Cages – K230872

Additional Predicate Devices:

- Shanghai Sanyou PEEK Cage System – K163422
- Shanghai Sanyou KEYSTONE PEEK Cage System – K211689

There are insignificant differences between the subject SWINGO-3D Lumbar Cage System and the predicate. The Indications for Use for predicate devices are all inclusive of the subject device. The materials and manufacturing for the subject device are identical to those of the predicate. There are slight differences in the geometry of the subject and predicate devices, but no new worst case is introduced. The subject device is provided sterile, identical to the predicate device. Thus, it can be concluded that the subject does not raise new questions about safety and effectiveness.

Performance Testing:

Bench performance testing including static and dynamic axial compression and static and dynamic compression shear per ASTM F2077-14. Subsidence testing was also performed per ASTM F2267-04.

All testing was performed on the predicate device. However, the subject devices do not introduce any new worst case and is thus substantially equivalent to the predicate. Therefore, all previously performed testing is applicable to the subject devices and no additional performance testing is needed.

Conclusion:

Based on the performance analysis and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.