April 20, 2026

ZheJiang Decans Medical Devices Co., Ltd.
Haifeng Liu
Registration Manager
No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District
Jiaxing City, Zhejiang Province 314031
China

Re: K253213
Trade/Device Name: SAGI Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: September 29, 2025
Received: March 20, 2026

Dear Haifeng Liu:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

COLIN O'NEILL -S

for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253213

Please provide the device trade name(s).

SAGI Cervical Cage System

Please provide your Indications for Use below.

The SAGI Cervical Cage System is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The SAGI Cervical Cage System is designed for use with autogenous bone graft to facilitate fusion and is to be implanted via an open, anterior approach.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

Preparation Date:	September. 28, 2025	
Submitter	ZheJiang Decans Medical Devices Co., Ltd. No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District, Jiaxing City, Zhejiang Province, 314031,P.R. China	
Contact	Haifeng Liu, Registration Manager ZheJiang Decans Medical Devices Co., Ltd. No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District, Jiaxing City, Zhejiang Province, 314031,P.R. China Postcode: 314031 Email: hfliu@decansmd.com Phone:+86 15210058659	
Subject Device	Trade name	SAGI Cervical Cage System
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Classification Name	Intervertebral body fusion device
	Product Codes	OVE
Primary Predicate Device	Manufacturer	STRYKER SPINE
	Trade name	Stryker Spine AVS® Anchor-C Cervical Cage System
	510(K) number	K102606
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Classification Name	Intervertebral body fusion device
	Product Codes	OVE
Additional Predicate Device	Manufacturer	DePuy Synthes
	Trade name	Synthes Zero-P
	510(K) number	K072981
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Classification Name	Intervertebral body fusion device
	Product Codes	OVE
Additional Predicate Device	Manufacturer	Synthes Spine Co., L.P.
	Trade name	Synthes Zero-P Variable Angle (VA)
	510(K) number	K112068
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Classification Name	Intervertebral body fusion device
	Product Codes	OVE
Additional Predicate Device	Manufacturer	ZheJiang Decans Medical Devices Co., Ltd.
	Trade name	Gemini Cervical Fusion Cage System

	510(K) number	K242195
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Classification Name	Intervertebral body fusion device
	Product Codes	ODP
Additional Predicate Device	Manufacturer	ZheJiang Decans Medical Devices Co., Ltd.
	Trade name	Gemini Medical Cage System
	510(K) number	K242267
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Classification Name	Intervertebral body fusion device
	Product Codes	MAX
Indications for use	The SAGI Cervical Cage System is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The SAGI Cervical Cage System is designed for use with autogenous bone graft to facilitate fusion and is to be implanted via an open, anterior approach.	
Device Description	SAGI Cervical Cage System(including Type I, II and III Zero-profile interbody fusion cage system) is a stand-alone interbody fusion device intended to be used with screws to stabilize the cervical spinal column and facilitate fusion. Each type is composed of a PEEK cage with a radiopaque marker, a titanium alloy anterior fixation plate and screws. The cage is preassembled with an anterior fixation plate. The cages are manufactured from medical grade Polyetheretherketone (PEEK-OPTIMA® LT1) as described by ASTM F2026, while the anterior fixation plate and screws are machined from Ti-6Al-4V titanium alloy per ISO 5832-3. In addition,tantalum markers conforming to ISO 13782 are embedded in the cages to help allow for radiographic visualization. The cage is available in sizes that vary in footprint sizes, heights, and lordotic angles to accommodate patient anatomy. The screws are available in various diameters and lengths. Screws engage the vertebral bodies by passing through the intervertebral body fusion device and into bone.	
Materials	PEEK,Tantalum and Ti6Al4V	
Patient Contact	Bone and surrounding tissue	
Contact Duration	Perminent, >30 days	
Sterilization Method	The implants are irradiation sterile provided and for single use. The surgical instruments are non-sterile provided, and validated manual cleaning and steam sterilization instructions are provided for the end user.	
Environment of Use	Healthcare facility/Hospital	
Single Use	Yes	
Summary of	The SAGI Cervical Cage System is substantially equivalent to the predicate	

indication for use and technological characteristics	devices when evaluating indication for use and technological characteristics. The subject device has the identical indication for use as the predicate device. The subject device and predicate devices are substantially equivalent with only minor differences in technological characteristics regarding: ● ZP-I and ZP-III interbody lordosis angle ● marker materials These differences do not raise new questions of safety and effectiveness.
Non-clinical test	Performance-bench test including： Static Torsion testing per ASTM F2077-24 Torsional Fatigue Testing per ASTM F2077-24 Axial Compression Testing per ASTM F2077-24 Compression Fatigue Testing per ASTM F2077-24 Static Compression-Shear Testing per ASTM F2077-24 Compression-Shear Fatigue Testing per ASTM F2077-24 Subsidence Testing per ASTM F2276-24 Axial Pullout Strength Testing per ASTM F543-23 Driving Torque Testing per ASTM F543-23 Torsional Properties Testing per ASTM F543-23 Sterilization： The subject device is sterilized using Gamma Radiation. The sterilization validation has been performed in accordance with the principles of ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, ISO 11137-2:2013 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose and ISO 11137-3:2017 Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routinecontrol. A sterility assurance level (SAL) of 10^{-6} has been demonstrated. A shelf-life of 5 years has been established based on accelerated aging testing.
Performance - Animal	No animal study data is submitted in this 510(k).
Performance - Clinical	No clinical study data is submitted in this 510(k).
Substantial Equivalence	The SAGI Cervical Cage System is substantially equivalent to the predicate devices when evaluating indication for use and technological characteristics with only minor differences. These differences do not raise new questions of safety and effectiveness.
Conclusion	The non-clinical data demonstrates the SAGI Cervical Cage System is substantially equivalent to the predicate device.