



October 8, 2024

ZheJiang Decans Medical Devices Co., Ltd.
% Xiaoqing Xue
Registration Engineer
Sinow Medical AS
Vestre Fantoftåsen 44
Bergen, 5072
Norway

Re: K242267

Trade/Device Name: Gemini Medical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 1, 2024
Received: August 1, 2024

Dear Xiaoqing Xue:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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

Indications for Use

510(k) Number (if known)
K242267

Device Name
Gemini Medical Cage System

Indications for Use (Describe)

The Gemini Medical Cage System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended to be used with supplemental fixation.

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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510(K) Summary

Preparation Date:	Sep. 25, 2024	
Submitter	ZheJiang Decans Medical Devices Co., Ltd. No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District, Jiaxing City, Zhejiang Province, 314031,P.R. China	
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Designated Submission Correspondent	Company: Sinow Medical AS Address: Vestre Fantoftåsen 44, 5072, Bergen, Norway Contact Person: Xiaoqing Xue Telephone: +86 15161196032 Email: xue@bergemed.com	
Subject Device	Trade name	Gemini Medical Cage System
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Classification Name	Intervertebral body fusion device
	Product Codes	MAX
	Common name for product codes	Intervertebral fusion device with bone graft, lumbar
Primary Predicate Device	Manufacturer	Medtronic Sofamor Danek USA. Inc.
	Trade name	CAPSTONE SPINAL SYSTEM
	510(K) number	K073291
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Classification Name	Intervertebral body fusion device
	Product Codes	MAX
Additional Predicate Devices	Manufacturer	DePuy Synthes
	Trade name /510(K) number	K101923, CONCORDE CURVE SYSTEM
		K100089, SYNTHES T-PAL SPACER
		K072791, SYNTHES ORACLE PLATE
	Regulatory Class	II
	Regulation Number	21 CFR 888.3080
	Product Codes	MAX
Classification Name	Intervertebral body fusion device	
Additional Predicate Device	Manufacturer	Medtronic Sofamor Danek USA. Inc.
	Trade name	CLYDESDALE SPINAL SYSTEM
	510(K) number	K132897
	Regulatory Class	II

	Regulation Number	21 CFR 888.3080
	Product Codes	MAX
	Classification Name	Intervertebral body fusion device
Indications for use	<p>The Gemini Medical Cage System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended to be used with supplemental fixation.</p>	
Device Description	<p>Gemini Medical Cage System is manufactured from a biocompatible polymer (Polyetheretherketone (PEEK)) material embedded with radiopaque tantalum marker pins, which allow the surgeon to radiographically determine the position of the implant, both intraoperatively and postoperatively. The System consists of PEEK lumbar cages of various shape and size, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. They are designed with angular teeth to allow the implant to grip the superior and inferior end plates. The top surface of the cages have anatomical design, parallel design and wedge-shaped design respectively to adapt various vertebrae anatomical scenarios. The hollow geometry of the implants allows them to be packed with autogenous bone graft in lumbar interbody fusion procedures. The cages are sterile provided and for single use. There are six models to accommodate different types of superior and inferior end plates depending on their technical design and shape, LF-I, LF-II, LF-III, LF-IV, LF-V and LF-VI. LF-I, LF-IV and LF-VI have curved top and bottom tooth surface, LF-II has flat top and bottom tooth surface, LF-III and LF-V have flat or wedge-shaped surface. LF-III, LF-IV and LF-V cages have a convex angle.</p>	
Summary of indication for use and technological characteristics	<p>The Gemini Medical Cage System is substantially equivalent to the predicate devices when evaluating indication for use and technological characteristics.</p> <p>The subject device has the identical indication for use as the predicate device. The subject device and predicate devices are substantially equivalent, differences do not raise new questions of safety and effectiveness.</p>	
Non-clinical test	<p>Performance-bench test including:</p> <p>Static Axial Compression Testing per ASTM F2077</p> <p>Dynamic Axial Compression Testing per ASTM F2077</p> <p>Static Compression Shear Testing per ASTM F2077</p> <p>Dynamic Compression Shear Testing per ASTM F2077</p> <p>Subsidence Test per ASTM F2267</p>	
Substantial Equivalence	<p>The Gemini Medical Cage System is substantially equivalent to the predicate devices when evaluating indication for use and technological</p>	

	characteristics with only minor differences. These differences do not raise new questions of safety and effectiveness.
Conclusion	The non-clinical data demonstrates the Gemini Medical Cage System is substantially equivalent to the predicate device.