November 4, 2024

ZheJiang Decans Medical Devices Co., Ltd.
Chen Liu
RA
No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District
Jiaxing, Zhejiang 314031
China

Re: K242195
Trade/Device Name: Gemini Cervical Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: July 26, 2024
Received: October 16, 2024

Dear Chen 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 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,

Ethan R. Naylor -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

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.

Submission Number *(if known)*

K242195

Device Name

Gemini Cervical Fusion Cage System

Indications for Use *(Describe)*

The Gemini Cervical Fusion Cage System is indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one levels from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Gemini Cervical Fusion Cage System requires additional supplemental fixation cleared for the cervical spine. The Gemini Cervical Fusion Cage System is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of nonoperative treatment.

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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510K Summary

1.SUBMITTER

ZheJiang Decans Medical Devices Co., Ltd.
No.2836 Xincheng Avenue, Gaozhao Street, Xiuzhou District, Jiaxing City, Zhejiang Province,314031 P.R. China
Contact Person:Chen Liu,RA
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Email:cliu@decansmd.com
Date Prepared:JUL/26/2024

2.DEVICE

Trade Name:Gemini Cervical Fusion Cage System
Classification :21 CFR 888.3080 Intervertebral body fusion device
Class:II
Product Code:ODP

3.PREDICATE DEVICE

Primary Predicate:CORNERSTONE® PSR Cervical Fusion System(K153373)

4.DEVICE DESCRIPTION

The Gemini Cervical Fusion Cage Systeme is an anterior cervical interbody device consisting of implants with various widths, heights and lengths to accommodate individual patient anatomy and graft material size. It is to be packed with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and is to be implanted via an open, anterior approach.

The Gemini Cervical Fusion Cage System is an implant constructed of medical grade Polyetheretherketone, (PEEK-OPTIMA® LT1) as described by ASTM F2026. The radiolucent PEEK-OPTIMA®material allows visualization of the defect site on radiography to assess bone growth and incorporates tantalum markers conforming to ISO13782 to permit verification of position. The Gemini Cervical Fusion Cage System is provided sterile via gamma irradiation for single use.Instruments are provided clean and non-sterile for steam sterilization at the user's facility.

5.INDICATION FOR USE

The Gemini Cervical Fusion Cage System is indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one levels from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Gemini Cervical Fusion Cage System requires additional supplemental fixation cleared for the cervical

spine. The Gemini Cervical Fusion Cage System is designed for use with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft, to facilitate fusion and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of nonoperative treatment.

6.COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject Gemini Cervical Fusion Cage System and the predicates share similar design features:

- Graft windows for packing autogenous or allogenic bone
- Serrations on the superior and inferior surfaces
- Comparable heights, widths, depths

The indication for use,design features, materials used, manufacturing, and sterilization methods are identical to the previously cleared CORNERSTONE® PSR Cervical Fusion System.

There are insignificant differences between the subject Gemini Cervical Fusion Cage System and the predicates. Performance analysis shows that the subject Gemini Cervical Fusion Cage System is expected to perform as well as the predicate devices.

7.PERFORMANCE DATA

Performance testing was conducted per ASTM F2077 and ASTM F2267. Specifically, Implant performed static and dynamic axial compression testing, static and dynamic compression shear testing, static and dynamic torsional testing and subsidence testing, Test results meet the acceptance criteria described in ISO 23089-2 *Implants for surgery - Preclinical mechanical assessment of spinal implants and particular requirements - Part 2: Spinal intervertebral body fusion devices*

8.CONCLUSION

Gemini Cervical Fusion Cage System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Thus, the subject device is substantially equivalent to the predicate device.