March 6, 2024

BioGend Therapeutics Co. Ltd.
Chienpei Chen
Senior Specialist
4F., No. 3-2 Park St., Nangang District
Taipei, 115
Taiwan

Re: K233075
Trade/Device Name: "BioGend" Interbody Fusion System 001 Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX,
Dated: December 6, 2023
Received: December 27, 2023

Dear Chienpei Chen:

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.

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)*
K233075

Device Name
"BioGend" Interbody Fusion System 001 Cage

Indications for Use *(Describe)*
The "BioGend" Interbody Fusion System 001 Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. This device is to be used with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone graft. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Patients should have at least six months of non-operative treatment prior to treatment with an intervertebral cage. "BioGend" Interbody Fusion System 001 Cage is to be implanted via a direct posterior approach. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA 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.

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510(k) SUMMARY

5.1 Type of Submission: Traditional

5.2 Date of Summary: 09/15/2023

5.3 Submitter: BioGend Therapeutics Co., Ltd.

Address: 4F, No. 3-2, Park St., Nangang Dist., Taipei City 115, Taiwan (R.O. C.)
Phone: +886-2-26558366
Contact: Chienpei Chen
(chienpei.chen@biogend.com.tw)

5.4 Identification of the Device:

Proprietary/Trade name:	"BioGend" Interbody Fusion System 001 Cage
Classification Product Code:	MAX
Regulation Number:	888.3080
Regulation Description:	Intervertebral Fusion Device With Bone Graft, Lumbar
Review Panel:	Orthopedic
Device Class:	II

5.5 Identification of the Predicate Device:

Predicate Device Name:	II-Type Intervertebral Spacer
Applicant:	Paonan Biotech. Co., Ltd.
Classification Product Code:	MAX
Regulation number:	888.3080
Device Class:	II
510(k) Number:	K180228

5.6 Indications for Use / Intended Use of the Device

The "BioGend" Interbody Fusion System 001 Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. This device is to be used with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone graft. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Patients should have at least six months of non-operative treatment prior to treatment with an intervertebral cage. "BioGend" Interbody Fusion System 001 Cage is to be implanted via a direct posterior approach. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

5.7 Description of the Device

"BioGend" Interbody Fusion System 001 Cage is designed to be inserted into the intervertebral body space of the spine as an adjunct to fusion. "BioGend"Interbody Fusion System 001 Cage consists of lumbar cages which are available in various heights and lengths to fit the patient's anatomical and physiological requirements. The superior and inferior surfaces of the "BioGend" cages have teeth to help prevent implant dislodgement or expulsion once placed in the desired location. The cages are made of polyetheretherketone (PEEK) which complies with ASTM F2026, and the radiographic markers incorporated into the cages are made of titanium alloy (Ti-6Al-4V ELI) conforming to ISO 5832-3 and ASTM F136. The cages are supplied sterile and intended for single use only. All implants should not be reused under any circumstances.

5.8 Non-clinical Testing

A series of tests were performed to assess the safety and effectiveness of the subject device. All test results demonstrate that the subject device meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

- Sterilization verification
- Shelf life
- Biocompatibility
- Performance testing

  The testing includes static and dynamic axial compression test, static compression-shear test, Compressive Subsidence test, static and dynamic torsional test, and expulsion test. These tests are compliance with the requirements of ASTM F2077-22, ASTM F2267-22 and FDA guidance "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device".

5.9 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence. The substantial equivalence of the finished "BioGend" Interbody Fusion System 001 Cage have been established through previous non-clinical performance testing.

5.10 Substantial Equivalence Determination

"BioGend" Interbody Fusion System 001 Cage submitted in this 510(k) file is substantially equivalent in indications for use/intended use, technological characteristics, and safety and performance claims to the cleared device, II-Type Intervertebral Spacer (K180228). Differences between the devices cited in this section do not raise any new issue of substantial equivalence.

Item	Subject Device	Predicate Device	Substantial Equivalence Discussion
Manufacturer	BioGend Therapeutics Co., Ltd.	Paonan Biotech. Co., Ltd.	
Trade Name	"BioGend" Interbody Fusion System 001 Cage	II-Type Intervertebral Spacer	
510(k) No.	(to be assigned)	K180228	
Indications for Use/Intended Use	The "BioGend" Interbody Fusion System 001 Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. This device is to be used with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone graft. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Patients should have at least six months of non-operative treatment prior to treatment with an intervertebral cage. "BioGend"	The II-Type Intervertebral Spacer is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. This device is to be used with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone graft. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). Patients should have at least six months of non-operative treatment prior to treatment with an intervertebral cage. The II-Type Intervertebral Spacer is to be implanted via a	***Same***

Item	Subject Device	Predicate Device	Substantial Equivalence Discussion
Manufacturer	BioGend Therapeutics Co., Ltd.	Paonan Biotech. Co., Ltd.	
Trade Name	"BioGend" Interbody Fusion System 001 Cage	II-Type Intervertebral Spacer	
510(k) No.	(to be assigned)	K180228	
	Interbody Fusion System 001 Cage is to be implanted via a direct posterior approach. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.	direct posterior approach. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.	
Sterile	Yes	Yes	***Same***
Main Material	Polyetheretherketone (PEEK)	Poly Ether Ether Ketone (PEEK)	***Same***
Dimensions	Height: 8.0 mm ~ 14.0 mm Length: 26, 28, 30, 32 and 36 mm	Height: 8.0 mm ~ 14.0 mm Length: 24, 26 and 28 mm	***Similar*** The performance of the subject device is not affected and meets the requirements. Thus, it would not affect the equivalence.
Mechanical Testing	Static and dynamic axial compression test, static compression-shear test, compressive subsidence test, static and dynamic torsional	Static and dynamic axial compression test, static torsion test, static compression-shear test, and subsidence test.	***Similar*** The performance of the subject device is not affected

Item	Subject Device	Predicate Device	Substantial Equivalence Discussion
Manufacturer	BioGend Therapeutics Co., Ltd.	Paonan Biotech. Co., Ltd.	
Trade Name	"BioGend" Interbody Fusion System 001 Cage	II-Type Intervertebral Spacer	
510(k) No.	(to be assigned)	K180228	
	test, and expulsion test.		and meet the requirements. Thus, it would not affect the equivalence.

5.11 Similarity and Difference

The "BioGend" Interbody Fusion System 001 Cage is compared with *II-Type Intervertebral Spacer*. The subject device has same indications for use/intended use, technological characteristics, and similar safety and performance to the predicate device. No specifications are significantly different between these two devices.

Furthermore, the subject device has undergone other safety and performance tests, and the results complied with the testing standards. Therefore, any differences between the subject device and the predicate device are insignificant and do not raise any problem of substantial equivalence. The subject device is substantially equivalent to the predicate device as it claims.

5.12 Conclusion

After analyzing non-clinical laboratory studies, safety and performance testing data, it can be concluded that the "BioGend" Interbody Fusion System 001 Cage is substantially equivalent to the predicate device.