January 11, 2019

Paonan Biotech Co., Ltd.
Vivi Tsai
Regulation Affair
3F, No. 50, Lane 258, Rueiguang Rd.
Neihu District, Taipei, 11491
Taiwan, R.O.C.

Re: K180228
Trade/Device Name: II-Type Intervertebral Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 4, 2018
Received: December 10, 2018

Dear Vivi Tsai:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180228

Device Name
II-Type Intervertebral Spacer

Indications for Use *(Describe)*

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 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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K180228

510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92.

Submitter Information:	Paonan Biotech. Co., Ltd. 3F, No. 50, Lane. 258, Rueiguang Rd., Neihu District, Taipei City, Taiwan, R.O.C.
Contact Person:	Vivi Tsai TEL: +886-2-2627-4366 FAX: +886-2-2627-4399 Email: vivi0921@paonan.com.tw
Date Prepared:	Nov. 15th , 2018
Trade Name:	II-Type Intervertebral Spacer
Common Name:	Intervertebral Spacer
Classification Name:	Intervertebral Fusion Device With Bone Graft (21 CFR 888.3080)
Device Class:	Class II
Panel:	Orthopedic
Product Code:	MAX
Predicate Devices:	Primary predicate device: Lumbar I/F Cage (P960025) Additional predicates: Capstone Spinal System (K073291) FORZA Spacer System (K103111)

Device Description:

II-Type Intervertebral Spacer consists of PEEK cages of various widths and heights, which include Ta markers, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone graft.

Intended Use:

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 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.

Technological Characteristics:

The II-Type Intervertebral Spacer implanted via posterior approach are intended to facilitate interbody arthrodesis. These cages allow restoration of the disc height and natural lordosis. Nerve-root decompression is also achieved by opening the neural foramen.

The II-Type Intervertebral Spacer are entirely made of Poly Ether Ether Ketone (PEEK), a biocompatible material with modulus characteristics similar to vertebral bone. They are fully radiolucent, which enables optimum follow-up with diagnostic imaging, as the interbody fusion progresses. Two metal wires at the opposite ends of the cage allow radiological confirmation of the cage position post operatively.

Non-Clinical Performance Data:

Paonan has submitted data from testing performed in compliance with ASTM F 2077-11 including static and dynamic axial compression test, static torsion test, static compression-shear test, and ASTM F 2267-04 subsidence test using samples each of a worst case construct demonstrate that the II-Type Intervertebral Spacer is substantially equivalent to legally marketed lumbar interbody fusion and is therefore appropriate for use in lumbar interbody fusion as described in the indication above.

Clinical Performance Data:

Clinical testing was not required for this submission.

Conclusion of Substantial Equivalence:

The II-Type Intervertebral Spacer has been demonstrated to be substantially equivalent to predicate system with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device