Paonan Biotech Co., Ltd.
Tony Lin
R&D Engineer
3F, No. 50, Lane 258, Rueiguang Rd.
Neihu District, Taipei City 11491
Taiwan

January 25, 2019

Re: K180230
Trade/Device Name: NEST Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 21, 2018
Received: December 26, 2018

Dear Mr. Lin:

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)*
K180230

Device Name
NEST Interbody System

Indications for Use *(Describe)*
The NEST Interbody System is indicated for interbody fusion with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should be skeletally mature and have six months of non-operative treatment. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s).

The NEST Interbody System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral 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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Paonan Biotech Co., Ltd.

NEST Interbody System

Traditional 510(k)

K180230
510(k) Summary

Submitted by	Paonan Biotech Co., Ltd. 3F., No. 50, Lane 258, Rueiguang Road, Neihu District 11491, Taipei City, Taiwan
Contact Person	Tony Lin R & D Engineer Phone: +886-2-26274366 #603 Email: linzw@paonan.com.tw
Date Prepared	January 19th, 2018
Common Name	Intervertebral body fusion device
Trade Name	NEST Interbody System
Proposed Class	Class II
Classification Name and Number	Intervertebral body fusion device, 21 CFR §888.3080
Product Code	MAX
Predicate Devices	Legally marketed predicate devices to which substantial equivalence is claimed: • Primary predicate: Stryker Spine Tritanium® PL Cage (k152304) • Additional predicate: Spineart JULIET® Ti (k153621) K2M Cascadia Interbody System (k150481) DePuy AcroMed, Inc. Lumbar I/F Cage® with VSP® Spinal System(P960025)
Device Description	The NEST Interbody System is an intervertebral body fusion cage which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow, rectangular implant consists of both solid and porous structures and serrations on the superior and inferior porous surfaces are for enhanced fixation.

	The implant is designed to be used with supplemental fixation with cleared for use in the lumbosacral spine. The implant is offered in a variety of sizes to accommodate a variety of patients' anatomy. NEST is additively manufactured from Ti6Al4V alloy (ASTM F3001) and is provided sterile.
Intended Use and Indications for Use	The NEST Interbody System is indicated for interbody fusion with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should be skeletally mature and have six months of non-operative treatment. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The NEST Interbody System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine
Summary of the Technological Characteristics	The subject NEST Cage and the predicates are identical in indications for use, surgical technique, manufacturing method and raw material. The subject NEST Cage and the predicates share similar design features: • Graft windows for packing autogenous bone • Serrations on the superior and inferior surfaces • Comparable heights, widths, depths, and lordotic angles, material
Summary of Non-Clinical Testing	Testing in compliance with: FDA's "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the NEST Cage and demonstrated substantially equivalent performance to the identified predicate devices. The following mechanical tests were performed: • Static Compression (per ASTM F2077)

	• Dynamic Compression (per ASTM F2077) • Static Compression Shear (per ASTM F2077) • Static Torsion (per ASTM F2077) • Subsidence (per ASTM F2267)
Conclusion	Based on the design features, the use of established well known materials, feature comparisons, indications for use, and results of the mechanical testing, the NEST Cage has demonstrated substantial equivalence to the identified predicate devices.