April 24, 2023

Paonan Biotech Co., Ltd.
Penny Huang
Associate Product Manager
3F, No.50, Lane 258, Rueiguang Road, Neihu District
Taipei City, 114062
Taiwan

Re: K220261
Trade/Device Name: NEST-C Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: March 22, 2023
Received: March 22, 2023

Dear Penny Huang:

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/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 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220261

Device Name
NEST-C Interbody System

Indications for Use *(Describe)*
The NEST-C Interbody System is indicated for use in cervical interbody fusion procedures with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one level or multiple contiguous levels from the C2 to T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have six weeks of non-operative treatment.
The NEST-C Interbody System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical 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-C Interbody System

Traditional 510(k)

510(k) Summary

Submitted by	Paonan Biotech Co., Ltd. 3F., No. 50, Lane 258, Rueiguang Road, Neihu District 11491, Taipei City, Taiwan
Contact Person	Penny Huang Phone: +886-2-26274366 #608 Email: pennyhuang@paonan.com.tw
Date Prepared	Jan.26,2022
Common Name	Intervertebral body fusion device
Trade Name	NEST-C Interbody System
Proposed Class	Class II
Classification Name and Number	Intervertebral body fusion device, 21 CFR §888.3080
Product Code	ODP
Predicate Devices	Legally marketed predicate devices to which substantial equivalence is claimed: • Primary predicate: AVS® AS PEEK Spacer (k142251) • Additional predicate: NEST Interbody System (k180230)
Device Description	The NEST-C Interbody System is intervertebral body fusion device with solid and porous structures that both are simultaneously built, using additive manufacturing method, from titanium alloy (Ti6Al4V ELI) powder per ASTM F3001. Offered in a number of footprints, heights and lordotic angles to adapt to a variety of patient anatomies. The implant consists of a hollow window for bone graft packing and serrations on the superior/inferior surfaces of the cage for enhanced fixation. The internal porous structure provides additional space for bone graft packing. NEST-C cage is intended to be used with supplemental spinal fixation

Paonan Biotech Co., Ltd.

NEST-C Interbody System

Traditional 510(k)

	systems that have been cleared for use in the cervical spine.
Intended Use and Indications for Use	The NEST-C Interbody System is indicated for use in cervical interbody fusion procedures with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one level or multiple contiguous levels from the C2 to T1 disc. DDD is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Patients should be skeletally mature and have six weeks of non-operative treatment. The NEST-C Interbody System is intended to be used with supplemental spinal fixation systems that have been cleared for use in the cervical spine.
Summary of the Technological Characteristics	The subject NEST-C Interbody System and the predicates are identical in indications for use, surgical technique, manufacturing method and raw material. The subject NEST-C Cage and the predicates share similar design features: • Hollow structure for packing autogenous bone graft and/or allogenous bone graft. • Serrations on the superior and inferior surfaces • Comparable heights, widths, lengths and material
Summary of Non-Clinical Testing	The worst case devices were subjected to mechanical testing. Testing included static compression, static compression shear, static torsion, dynamic compression, dynamic torsion, and subsidence per ASTM F2077-22 and F2267-04. NEST-C Interbody System is the same as the predicate device NEST Interbody System in formulation, manufacturing processing, sterilization, and geometry. According to biocompatibility evaluation, current submission met the biocompatibility requirements of ISO

	10993-1 and is safe for clinical use. These results demonstrate that the devices are substantially equivalent to the identified predicate devices.
Conclusion	NEST-C Interbody System has demonstrated substantial equivalence to the identified predicate devices regarding the design features, materials used, manufacturing, sterilization, indications for use, and results of the mechanical testing.