July 25, 2018

Paonan Biotech Co., Ltd.
Ms. Vivi Tsai
Regulatory Affairs
3F, No. 50, Lane 258, Rueiguang Road
Neihu District, Taipei City 114
TAIWAN

Re: K180226
Trade/Device Name: TREND II Spinal Fixation System- STEP Series
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: July 13, 2018
Received: July 13, 2018

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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,

Ronald P. Jean -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)*
K180226

Device Name

TREND II Spinal Fixation System - STEP Series

Indications for Use *(Describe)*

TREND II Spinal Fixation System - STEP Series is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion using autograft or allograft. This system is intended for posterior, non-cervical pedicle fixation of the thoracic, lumbar, and sacral/iliac spine (T1-Sacrum/Ilium) for the following indications:

- Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Degenerative Spondylolisthesis with objective evidence of neurologic impairment
- Fractures
- Dislocation
- Scoliosis
- Kyphosis
- Spinal tumor
- Failed previous fusion (pseudarthrosis)

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

ADMINISTRATIVE INFORMATION

Manufacturer Name Paonan Biotech Co.,Ltd.

Manufacturer Address 3F, No.50, Lane.258, Rueiguang Rd.,
Neihu District, Taipei City, Taiwan,R.O.C.

DEVICE NAME TREND II Spinal Fixation System- STEP Series

Contact Person/Date Prepared Vivi Tsai/July 20, 2018

Common / Classification Name

Thoracolumbosacral Pedicle Screw System, 21 CFR 888.3070, Class II

Product code: NKB

Predicate Device

Primary predicate device: “Paonan” Armstrong Posterior Spinal Fixation System (K161225)

	Subjective Device	Primary Predicate Device	Additional predicates
System name	TREND II Spinal Fixation System-STEP Series	“Paonan” Armstrong Posterior Spinal Fixation System	MYKRES Spinal System
510(k) Number	--	K161225	K051704
Manufacturer	PAONAN	PAONAN	Showa Ika
Materials	Ti6Al4V	Ti6Al4V	Ti6Al4V
Classification	888.3070	888.3070	888.3070
Product Code	NKB	NKB	MNI
Subsequent Product Code	N/A	N/A	KWP, MNH
Required Standard	Ti6Al4V-ISO 5832-3, ASTMF 136	Ti6Al4V-ISO 5832-3, ASTMF 136	Ti6Al4V-ISO 5832-3, ASTMF 136
Application	thoracic, lumbar to sacrum	thoracic, lumbar to sacrum	thoracic, lumbar to sacrum
Intend Use	To provide	To provide	To provide

	immobilization and stabilization for posterior, non-cervical, pedicle fixation of the thoracic, lumbar, and sacral/iliac spine (T1 – Sacrum/Ileum) in skeletally mature patients.	immobilization and stabilization for posterior, non-cervical, pedicle fixation of the thoracic, lumbar, and sacral/iliac spine (T1 – Sacrum/Ileum) in skeletally mature patients.	immobilization and stabilization for posterior, non-cervical, pedicle and non-pedicle fixation of the thoracic, lumbar, and sacral spine in skeletally mature patients.
Indication	● Degenerative disc diseases ● Degenerative Spondylolisthesis ● Fractures ● Dislocation ● Scoliosis ● kyphosis ● Spinal tumor ● Failed previous fusion (pseudarthrosis)	● Degenerative disc diseases ● Degenerative Spondylolisthesis ● Fractures ● Dislocation ● Scoliosis ● kyphosis ● Spinal tumor ● Failed previous fusion (pseudarthrosis)	● Degenerative Spondylolisthesis ● Fractures ● Dislocation ● Scoliosis ● kyphosis ● Spinal tumor ● Failed previous fusion (pseudarthrosis)
Component	Cannulated screw, non-cannulated screw, rod, set screw, hook, transverse link	Cannulated screw, mono-axial screw, poly-axial screw, block, washer, rod, link, connector, set screw	rods, mono-axial screw, poly-axial screw, hooks and connectors
Sterilization	Non-sterile	Non-sterile	Non-sterile
Mechanical Test	Static and dynamic compression test, Static Torsional Test per ASTM F1717, and Pullout Test per ASTM F543	Static and dynamic compression bending Test, Static Torsional Test per ASTM F1717 Axial gripping capacity test and Axial torque gripping capacity test per ASTM F1798	Static compression, static torsion, and dynamic compression per ASTM F1717

Device Description

TREND II Spinal Fixation System- STEP Series includes cannulated screw, non-cannulated screw, rod, set screw, hook, and transverse link. Different types or sizes of these implants are available so that adaptations can be utilized to take into account the unique pathology

of individual patients. The system components are manufactured from Ti6Al4V based which complies with ASTM F136 /ISO 5832-3.

Indications for Use

TREND II Spinal Fixation System- STEP Series is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion using autograft or allograft. This system is intended for posterior, non-cervical pedicle fixation of the thoracic, lumbar, and sacral/iliac spine (T1 – Sacrum/Ilium) for the following indications:

– Degenerative disc diseases (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
– Degenerative Spondylolisthesis with objective evidence of neurologic impairment.
– Fractures
– Dislocation
– Scoliosis
– Kyphosis
– Spinal tumor
– Failed previous fusion (pseudarthrosis)

Performance Data:

Mechanical testing including static/dynamic axial compression bending test and static torsion test for spinal corpectomy model were conducted referring to ASTM F1717 to demonstrate substantial equivalence to the predicate system. In addition, pullout test of multiaxial screw was performed according to ASTM F543. The results demonstrate substantial equivalence of TREND II Spinal Fixation System- STEP Series to the predicate device(s).

Conclusion of Substantial Equivalence:

The TREND II Spinal Fixation System- STEP Series has been demonstrated to be substantially equivalent to the predicate(s) 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(s).