



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

August 11, 2017

Re: K161225

Trade/Device Name: "Paonan" Armstrong Posterior Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: May 16, 2017
Received: July 18, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161225

Device Name

"Paonan" Armstrong Posterior Spinal Fixation System

Indications for Use (Describe)

"Paonan" Armstrong Posterior Spinal Fixation System 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/ilium 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) 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 114, Taiwan

DEVICE NAME "Paonan" Armstrong Posterior Spinal Fixation System

Contact Person/Date Prepared Vivi Tsai / August 3, 2017

Common/Classification Name

Thoracolumbosacral Pedicle Screw System, 21 CFR 888.3070, Class II

Product code: NKB

Predicate Device

Primary predicate device: MYKRES Spinal System (K051704)

	Subjective Device	Primary Predicate Device	Additional predicates	Additional predicates	Additional predicates
System name	"Paonan" Armstrong Posterior Spinal Fixation System	MYKRES Spinal System	SYNERGY Spinal System VLS Open	Ibis™ Pedicle Screw System	Depuy MOSS Miami Spinal System
Manufacturer	Paonan Biotech. Co.	Showa Ika Kohgyo Co.	Cross Medical Products, Inc. (Interpore Cross International)	Ortho Development Corp.	Depuy Acromed
510(k) Number Classification	K161225	K051704	K950099, K973836, K993808	K142146, K162995	K955348, K983583, K011182, K030383
	888.3070	888.3070	888.3070	888.3070	888.3070, 888.3050
Product Code	NKB	MNI	MNH	NKB	MNH
Subsequent Product Codes	N/A	KWP, MNH	KWP, KWQ	MNH, MNI	KWP, MNI, KWQ
Intended Use	To provide immobilization and stabilization for posterior, non-cervical, pedicle fixation of the thoracic, lumbar, and sacral/iliac spine (T1 – Sacrum/Ileum) in	To provide immobilization and stabilization for posterior, non-cervical, pedicle and non-pedicle fixation of the thoracic, lumbar, and sacral spine in skeletally mature patients.	To provide immobilization and stabilization for posterior, anterior, non-cervical, pedicle and non-pedicle fixation of the thoracic, lumbar, and sacral spine in skeletally mature	To provide immobilization and stabilization for posterior, non-cervical pedicle fixation of the thoracic, lumbar, and sacral/iliac spine (T1 –	To provide immobilization and stabilization for posterior, anterior, non-cervical, pedicle and non-pedicle fixation of the thoracic, lumbar, and sacral spine in skeletally mature

	skeletally mature patients.		patients.	Sacrum/Ileum) in skeletally mature patients	patients.
Indications	<ul style="list-style-type: none"> ● Degenerative disc diseases ● Degenerative Spondylolisthesis ● Fractures ● Dislocation ● Scoliosis ● kyphosis ● Spinal tumor ● Failed previous fusion (pseudarthrosis) 	<ul style="list-style-type: none"> ● Degenerative Spondylolisthesis ● Fractures ● Dislocation ● Scoliosis ● kyphosis ● Spinal tumor ● Failed previous fusion (pseudarthrosis) 	<p>Indications for posterior non-cervical, pedicle fixation:</p> <ul style="list-style-type: none"> ● Degenerative Spondylolisthesis ● Fracture ● Dislocation ● Scoliosis ● kyphosis ● Spinal tumor ● Failed previous fusion (pseudarthrosis) 	<ul style="list-style-type: none"> ● Degenerative disc disease (DDD) ● Degenerative Spondylolisthesis ● Trauma (fracture or dislocation) ● Spinal tumor ● Failed previous fusion (pseudarthrosis) ● Spinal stenosis ● Spinal deformities or curvatures such as scoliosis, kyphosis, or lordosis 	<p>Indications for posterior non-cervical, pedicle fixation:</p> <ul style="list-style-type: none"> ● Degenerative Spondylolisthesis ● Fractures ● Dislocation ● Scoliosis ● kyphosis ● Spinal tumor ● Failed previous fusion (pseudarthrosis)
Component	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	rods, mono-axial screw, poly-axial screw, hooks and connectors, washers	Cannulated screw, mono-axial screw, poly-axial screw, set screw, rod,	Rods, screws, hook, transverse connector, axial connectors, staple washer and sacral extender
Materials	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V, CP Ti, Stainless Steel	Ti-6Al-4V	Ti-6Al-4V, Stainless Steel
Mechanical testing	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	Static compression, static torsion, and dynamic compression per ASTM F1717	Static compression, static torsion, and dynamic compression per ASTM F1717 Axial torque gripping capacity test per ASTM F1798	Static compression, static torsion, and dynamic compression per ASTM F1717
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile

Device Description

“Paonan” Armstrong Posterior Spinal Fixation System includes pedicle screws, rods, cross connectors, and associated instruments. 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

“Paonan” Armstrong Posterior Spinal Fixation System 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 cropectomy model were conducted referring to ASTM F1717 to demonstrate substantial equivalence to the predicate system. In addition, axial and torsional gripping capacity of Cross Link and Connecting Block interconnection mechanism were performed according to ASTM F1798. The results demonstrate substantial equivalence of the “Paonan” Armstrong Posterior Fixation System to the predicate device.

Conclusion of Substantial Equivalence:

The “Paonan” Armstrong Posterior Fixation System 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.