Orthopeasia Co., Ltd
℅ Joseph Azary
Regulatory Consultant
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

August 30, 2024

Re: K240180
Trade/Device Name: Orthopeasia Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: August 1, 2024
Received: August 1, 2024

Dear Joseph Azary:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.08.30 14:41:21 -04'00'
for

Colin O'Neill, M.B.E.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240180

Device Name

Orthopeasia Spinal Fixation System

Indications for Use *(Describe)*

The Orthopeasia Spinal Fixation System is intended to provide immobilization and stabilization of the posterior non-cervical spine (T1-S2/Illium) in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities:
- Degenerative disc disease (defied as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies);
- Degenerative spondylolisthesis with objective evidence of neurologic impairment;
- Trauma (i.e., fracture or dislocation);
- Deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis);
- Tumor;
- Stenosis;
- Failed previous fusion (pseudarthrosis)

The Orthopeasia Spinal Fixation System is also indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebral joint in skeletally mature patients receiving fusion by autogenous bone graft having the device fixed or attached to the lumbar and sacral spine (L3 to sacrum), with removal of the implants after the attainment of a solid fusion.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Traditional 510(k)
Orthopeasia Spinal Fixation System

1. SUBMITTER/510(K) HOLDER

Orthopeasia Co., Ltd.
33/15 Moo 10, Theparak Road
Bangpla, Bangplee, Samutprakarn
TH-10540 Thailand

Submission Contact

Joseph Azary
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, CT 06484

Email: jazary@erols.com
Alternate Email: jazary@aztechregulatory.com

Telephone: (203) 242-6670

Date Prepared: August 29, 2024

Reason for 510(k): New device / Initial Submission

2. DEVICE NAME

Proprietary Name:	Orthopeasia Spinal Fixation System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Common Name:	Thoracolumbosacral Pedicle Screw System
Classification Regulation:	21 CFR 888.3070
Product Code:	NKB
Classification:	Class 2
Medical Specialty (Panel):	Orthopedic

3. PREDICATE DEVICES

Type of Predicate	Device Name	Manufacturer	510(k) Number Product Code
Primary	Firebird Spinal Fixation System	Orthofix, Inc	K130932 NKB, KWP, OSH
Additional Predicate	LOPSA IS Spinal Fixation System	Corentec Co., Ltd	K200267 NKB, KWQ

4. DEVICE DESCRIPTION

The Orthopeasia Spinal Fixation System is a temporary, multiple component system comprised of a variety of non-sterile, single use components, made of titanium alloy or cobalt chrome alloy, that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screw fixation to the non-cervical spine. The system consists of a variety of shapes and sizes of screws, rods, crosslinks and connectors to create a rigid construct as an adjunct to fusion for temporary internal fixation and stabilization of the thoracic, lumbar and sacral spine.

The Orthopeasia Spinal Fixation System is this submission comprises of the following components,

A. Pedicle screws (Mono-axial and Poly-axial), standard, cannulated, with:
    a. Monoaxial screw diameters from 5.5mm to 8.5mm
    b. Polyaxial screw diameters from 5.5mm to 8.5mm
    c. Monoaxial length range from 20mm to 55mm
    d. Polyaxial length range from 20mm to 100mm
    e. Made up of titanium alloy (ASTM F136).

B. Straight rods of diameter of 5.0 mm made up of cobalt chrome alloy (ASTM F1537)

C. Crosslinks and connectors made up of titanium alloy (ASTM F136).

5. INDICATIONS FOR USE

The Orthopeasia Spinal Fixation System is intended to provide immobilization and stabilization of the posterior non-cervical spine (T1-S2/Illium) in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities:

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- Failed previous fusion (pseudoarthrosis)

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6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject device has similar indications, materials, components, sterility status, single use, dimensions and instrumentation as compared to predicate devices. The differences include some minor differences in the wording of the indications for use, the additional predicate can be used for pediatric, and the subject devices are offered in longer lengths. Based on the testing to consensus standards (including worst case) and comparison to predicate devices, we conclude the differences do not impact safety or efficacy of the devices.

The minor differences include that primary predicate (Firebird) has a subset that can be used for pediatric patients, whereas the Firebird and Orthopeasia systems are for skeletally mature patients.

The technological design features of the subject Orthopeasia Spinal Fixation System is substantially equivalent to the predicate devices. The technological design features of the subject implants were compared to the predicates in intended use, indications for use, design, function, and technology and it was demonstrated that they are substantially equivalent.

7. PERFORMANCE TESTING

The Orthopeasia devices were subjected to a variety of testing including:

- Biocompatibility Evaluation per ISO 10993-1 (refer to Section 15 Biocompatibility)
- Sterilization Validation (refer to Section 14 Sterilization and Shelf Life)

In addition to the above referenced testing, the device was subjected to the testing outlined below.

Test Name	Test Description and Objective	Test Results / Summary
Static and Dynamic Compression Bending	Testing to ASTM F1717 to determine the mechanical properties of spinal implant assemblies in a vertebrectomy model under static and dynamic axial compression.	The results were above the range reached by implants of the additional predicate (lumbar polyaxial device).
Static axial and torsion grip test	Testing to ASTM F1798	The results were within the range reached by predicate devices. Therefore, the results passed.

8. CONCLUSION

The information presented supports substantial equivalence of the Orthopeasia Spinal Fixation System to the predicate device based on similarities in intended use, design, principles of operation and performance specifications.

The company concluded that based on testing, compliance to consensus standards, the indications for use, technological characteristics, and comparison to predicate devices, Orthopeasia Co., Ltd. found that the subject device is substantially equivalent to the predicate devices.