-DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 30, 2017

Ortho Development Corporation
Ms. Lindsay Martin
Manager, Regulatory Affairs
12187 South Business Park Drive
Draper, Utah 84020

Re: K162995
Trade/Device Name: Ibis® Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: January 10, 2017
Received: January 11, 2017

Dear Ms. Martin:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K162995

Device Name
Ibis® Pedicle Screw System

Indications for Use *(Describe)*
The Ibis® Pedicle Screw 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/Ileum) for the following indications:

1) Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2) Degenerative Spondylolisthesis with objective evidence of neurologic impairment
3) Trauma (fracture or dislocation)
4) Spinal tumor
5) Failed previous fusion (pseudarthrosis)
6) Spinal stenosis
7) Spinal deformities or curvatures such as scoliosis, kyphosis, or lordosis

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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# 510(k) Summary

| | |
|---|---|
| **Name of Sponsor:** | Ortho Development Corporation<br>12187 South Business Park Drive<br>Draper, Utah 84020 |
| **510(k) Contact:** | Lindsay Martin<br>Manager, Regulatory Affairs<br>Telephone: (801) 553-9991<br>Facsimile: (801) 553-9993<br>Email: LMartin@orthodevelopment.com |
| **Date Prepared:** | March 27, 2017 |
| **Proprietary Name:** | Ibis® Pedicle Screw System |
| **Common Name:** | Thoracolumbosacral Pedicle Screw System |
| **Classification:** | 21 CFR 888.3070 |
| **Device Product Code:** | NKB |
| **Class:** | Class II |
| **Primary Predicate Device:** | Ibis® Pedicle Screw System (K142146)<br>*Ortho Development Corporation* |
| **Additional Predicate Devices:** | Pagoda® Pedicle Screw System (K131785)<br>*Ortho Development Corporation*<br><br>Additions to the EXPEDIUM® and VIPER® Systems (K101993)<br>*Depuy Spine, Inc* |

**Description**

The Ibis® Pedicle Screw System consists of bulleted rods; cannulated polyaxial, monoaxial, extended length (Ibis® XL) and extended tab screws; and set screws; which can be variously assembled to provide immobilization of the thoracolumbar and lumbosacral spine. The Ibis® Pedicle Screw System maintains compatibility with the Pagoda Pedicle Screw System. All components are made from Titanium Alloy (Ti6Al4V).

**Indications:**

The Ibis® Pedicle Screw 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:

1. Degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
2. Degenerative Spondylolisthesis with objective evidence of neurologic impairment
3. Trauma (fracture or dislocation)
4. Spinal tumor
5. Failed previous fusion (pseudarthrosis)
6. Spinal stenosis
7. Spinal deformities or curvatures such as scoliosis, kyphosis, or lordosis

**Basis for Substantial Equivalence:**

The Ibis® XL Cannulated Polyaxial Screws are a line extension of the Ibis® Pedicle Screw System and have the following similarities to those which previously received 510(k) concurrence (K142146):

- have the same indicated use,
- incorporate the same basic polyaxial ball-socket and screw thread design,
- incorporate the same materials,
- have the same interconnection components (set screw and 5.5mm bulleted rod),
- have the same shelf life, and
- are packaged and sterilized using the same materials and processes.

In summary, the Ibis® XL Cannulated Polyaxial Screws described in this submission are, in our opinion, substantially equivalent to the predicate device.

**Nonclinical Test Summary:**

The following mechanical tests were conducted:

- Static Compression Bending in accordance with ASTM F1717 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model"
- Dynamic Compression Bending in accordance with ASTM F1717 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model"
- Axial Torque Gripping Capacity in accordance with ASTM F1798 "Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants"

**Conclusions:**

Ibis® XL Cannulated Polyaxial Screw has substantially the same intended use, indications for use, materials, general dimensions, performance, and principles of operation as the predicate devices.