510(k) Summary

NAME OF SPONSOR:	Ortho Development® Corporation 12187 South Business Park Drive Draper, Utah 84020
510(k) CONTACT:	Tom Haueter Regulatory Affairs Manager Telephone: (801) 553-9991 Facsimile: (801) 553-9993 Email: thaueter@orthodevelopment.com
DATE PREPARED:	29 May, 2013
PROPRIETARY NAME:	Pagoda™ Pedicle Screw System
COMMON NAME:	Pedicle Screw Spinal System
CLASSIFICATION:	21 CFR Sec. 888.3070 Pedicle screw fixation
DEVICE CLASS:	Class III
DEVICE PRODUCT CODE:	NKB MNI MNH
PREDICATE DEVICES:	Pangea (K052123) *Synthes Orthopedics* Tiger (K113058) *Corelink, LLC* Synergy Helical Flange Plug (K041449) *Interpore Cross, LLC* MOSS Miami (K964024) *Depuy Motech*

AUG 20 2013

Description

The Pagoda™ Pedicle Screw System consists of rods, polyaxial screws, reduction screws, monoaxial screws, set screws, transverse connectors, and offset connectors which can be variously assembled to provide immobilization of the thoracolumbar and lumbosacral spine. All components are made from Titanium Alloy (Ti6Al4V).

Indications

The Pagoda™ 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, noncervical pedicle fixation of the thoracic, lumbar, and sacral/iliac spine (T1 – S1/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

Basis for Substantial Equivalence

Pagoda™ Pedicle Screw System was evaluated in accordance with FDA Documents, *Guidance for Industry and FDA Staff; Spinal System 510(k)s, May 3, 2004*, and has been found to meet criteria defined in the guidance documents.

The following non-clinical tests were conducted:

- Static and dynamic compression testing per ASTM F1717
- Static torsion testing per ASTM F1717

Conclusions

Based on similarities in intended use, design, materials, manufacturing methods, and packaging, Pagoda™ Pedicle Screw System has demonstrated that it is substantially equivalent to the previously cleared predicate devices. Mechanical test results demonstrate that the proposed Pagoda™ Pedicle Screw System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Tom Haueter
Regulatory Affairs Manager
Ortho Development® Corporation
12187 South Business Park Drive
Draper, Utah 84020

August 20, 2013

Re: K131785
Trade/Device Name: Ortho Development® Pagoda™ Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: June 11, 2013
Received: June 18, 2013

Dear Mr. Haueter:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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 yours,

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): K131785

Device Name: Ortho Development® Pagoda™ Pedicle Screw System

Indications for Use:

The Pagoda™ 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, noncervical pedicle fixation of the thoracic, lumbar, and sacral/iliac spine (TI – S1/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

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131785