K110321

510(k) Summary
for the TIGER™ Spine System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the TIGER™ Spine System

Date Prepared: January 28, 2011

MAY 25 2011

1. **Submitter:**
Corelink, LLC
10805 Sunset Office Drive, Suite 300
St. Louis, MO 63127

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** **TIGER™ Spine System**
Common Name: **pedicle screw system**
Classification Name: orthosis, spinal pedicle fixation / orthosis, spondylolisthesis spinal fixation
MNI/MNH
21 CFR section 888.3070
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
ISOBAR (Scient'x - K990118/K013444)
ZODIAC™ Polyaxial Spinal Fixation System (Alphatec - K042673)
Array Spinal System (Biomet - K033312/K061563)

4. **Description of the device:**
The TIGER™ Spine System is comprised of polyaxial pedicle screws, rods and crosslinks. The TIGER™ Spine System can be used for single or multiple level fixations. The pedicle screws are available in various lengths and diameters. The rods are available in straight and pre-lordosed (curved) configurations. The system has variable length cross connectors.

Materials:
Ti-6Al-4V ELI conforming to ASTM F136

Function:
A posterior pedicle screw system designed for temporary stabilization of the anterior spine during the development of spinal fusion.

5. **Substantial equivalence claimed to predicate devices**

The TIGER™ Spine System is substantially equivalent to the ISOBAR and ZODIAC™ in terms of intended use, design, materials used, mechanical safety and performances. The table below compares the features and characteristics of the TIGER™ Spine System to these predicate devices.

Items \ Device Name	TIGER™ Spine System	ISOBAR	ZODIAC™ Polyaxial Spinal Fixation System	Array Spinal System
Sponsor	Corelink LLC	Scient'x	Alphatec Spine Co.	Biomet
510(k) Number	N/A	K990118/K013444	K042673	K033312/K061563
Device Classification Name	orthosis, spinal pedicle fixation per MNI 888.3070 orthosis, spondylolisthesis spinal fixation per MNH 888.3070	orthosis, spinal pedicle fixation per MNI 888.3070 orthosis, spondylolisthesis spinal fixation per MNH 888.3070	orthosis, spinal pedicle fixation per MNI 888.3070 orthosis, spondylolisthesis spinal fixation per MNH 888.3070	orthosis, spinal pedicle fixation per MNI 888.3070 orthosis, spondylolisthesis spinal fixation per MNH 888.3070
Product Code	MNI, MNH	MNI, MNH	MNI, MNH	MNI, MNH
Class	Class II per 21 CFR 888.3070/888.3050	Class II per 21 CFR 888.3070/888.3050	Class II per 21 CFR 888.3070/888.3050	Class II per 21 CFR 888.3070/888.3050
Straight rods **Pre-bent rods**	Yes Yes	Yes No	Yes Yes	Yes Yes
Rod material	Ti-6Al-4V ELI per ASTM F136	Ti-6Al-4V per ASTM F136	Ti-6Al-4V per ASTM F136	CP titanium Ti-6Al-4V per ASTM F136
Screw loading	Tulip top loading	Tulip top loading	Tulip top loading	Tulip top loading
Screw material	Ti-6Al-4V per ASTM F136	Ti-6Al-4V per ASTM F136	Ti-6Al-4V per ASTM F136	Ti-6Al-4V per ASTM F136
Polyaxial	Yes	Yes	Yes	Yes
Crosslinks - length	Yes	Yes	Yes	?
Sterility	None sterile, single use only			

The following devices were used as predicates for test result purposes:

- Synergy VLS – open (DePuy)
- Moss Miami SS K000536 (DePuy)
- Rogozinski K884263 (Smith & Nephew)
- ISOLA/MONARCH (DePuy)
- Valeo Pedicle Screw System K072022 (Amedica)

6. **Intended Use:**

The TIGER™ Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: fracture, dislocation, failed previous fusion (pseudoarthrosis), spinal stenosis, degenerative spondylolisthesis with objective evidence of neurological impairment, spinal deformations such as scoliosis or kyphosis and loss of stability due to tumors.

When used as a pedicle screw system, the TIGER™ Spine System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

7. **Non-clinical Test Summary:**

The following tests were conducted:

- Static and dynamic compression and static torsion per ASTM F1717.

8. **Clinical Test Summary**

No clinical studies were performed

9. **Conclusions Nonclinical and Clinical**

TIGER™ Spine System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Corelink, LLC
% The OrthoMedix Group, Inc.
Mr. J. D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

MAY 25 2011

Re: K110321
Trade/Device Name: TIGER™ Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: April 15, 2011
Received: April 19, 2011

Dear Mr. Webb:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110321

Device Name: TIGER™ Spine System

Indications for Use:

The TIGER™ Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as a pedicle screw system, the TIGER™ Spine System is intended for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebrae in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110321