

MAR 29 2012

**510(k) Summary**

**Device Trade Name:** TIGER™ Spine System

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

**Contact:** Justin Eggleton  
Musculoskeletal Clinical Regulatory Advisers, LLC  
1331 H Street NW, 12<sup>th</sup> Floor  
Washington, DC 20005  
Phone: (202) 552-5800  
Fax: (202) 552-5798

**Date Prepared:** September 28, 2011

**Common Name:** Pedicle screw spinal system

**Classification:** 21 CFR 888.3070

**Class:** III

**Product Code:** NKB, MNH, MNI

**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/iliac spine (T1 – S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

**Device Description:**

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. The implants are manufactured from Ti6Al4V alloy.

The purpose of this 510(k) is to expand the Indications For Use statement to included Degenerative Disc Disease (DDD).

**Predicate Devices:**

The TIGER™ Spine System was shown to be substantially equivalent to previously cleared devices (K110906 and K110321).

**Substantial Equivalence:**

Testing performed on this device indicates that the TIGER™ Spine System is substantially equivalent to predicate devices. Mechanical testing of the system included static and dynamic compression bending testing and static torsion testing per ASTM F1717, as well as, a clinical literature analysis.

**Conclusion**

The TIGER™ Spine System was shown to be substantially equivalent to previously cleared devices with respect to its indications for use, design, function, and materials.



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

Corelink, LLC  
% Musculoskeletal Clinical Regulatory Advisers, LLC  
Mr. Justin Eggleton  
1331 H Street Northwest, 12<sup>th</sup> Floor  
Washington, District of Columbia 20005

MAR 29 2012

Re: K113058  
Trade/Device Name: TIGER<sup>(TM)</sup> Spine System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system  
Regulatory Class: III  
Product Code: NKB, MNH, MNI  
Dated: March 5, 2012  
Received: March 6, 2012

Dear Mr. Eggleton:

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

Page 2 - Mr. Justin Eggleton

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" (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  
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):

K113058

Device Name: TIGER™ Spine System

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/ilic spine (T1 – S1/Ileum): degenerative disc disease (defined as discogenic back pain with degeneration of disc confirmed by history and radiographic studies), degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

Prescription Use   
(Part 21 CFR 801 Subpart D)

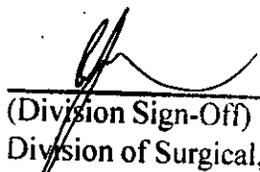
AND/OR

Over-The-Counter Use   
(21 CFR 801 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 K113058