510(k) SUMMARY
Titan Spine's Endoskeleton® TC

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

JUL 2 9 2010

Titan Spine, LLC
Mequon Research Center
6140 W. Executive Drive, Suite A
Mequon, WI 53092

Contact: Kevin Gemas
Phone: 866-822-7800

Date Prepared: March 30, 2010

Name of Device and Name/Address of Sponsor

Endoskeleton® TC

Titan Spine, LLC
Mequon Research Center
6140 W. Executive Drive, Suite A
Mequon, WI 53092

Common or Usual Name

Intervertebral body fusion device

Classification Name

21 CFR §888.3080 Intervertebral body fusion device
ODP
Class II

Device Description

The Endoskeleton® TC is a cervical intervertebral body fusion device. The system is comprised of a variety of implant sizes to accommodate various patient anatomy and pathology. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI). The center of the implant is hollow and is to be filled with autograft material. The design incorporates "windows" through the implant to permit visualization of the graft material and, over time, formation of new bone.

Predicate Devices

The Endoskeleton® TC was shown to be substantially equivalent to legally marketed predicate devices. The predicate devices include the BAK/C® Interbody Device by Zimmer Spine/Spine-Tech (P980048), the Phantom™ Plus Cage System by US Spine (K082801), the Zeus by Interbody Innovations (K081614), and the Aesculap® CeSpace PEEK Spinal Implant System (K083311).

Intended Use / Indications for Use

The Endoskeleton® TC is indicated for use for anterior cervical interbody fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C-3 to C-7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The Endoskeleton® TC is indicated to be used with supplemental fixation and autograft bone.

Summary of Non-Clinical Testing

The following mechanical testing was performed: static and dynamic axial compression, static and dynamic compression shear, and static and dynamic torsion per ASTM F2077; subsidence testing per ASTM F2267; and expulsion testing as recommended by the FDA Class II Special Controls Guidance Document: Intervertebral Body Fusion Device. The pre-clinical testing performed indicated that the Endoskeleton® TC is adequate for the intended use.

Substantial Equivalence

The Endoskeleton® TC has the same intended use and substantially similar indications for use, technological characteristics and principles of operation as the identified predicate devices. There are no significant differences between the Endoskeleton® TC and other systems currently being marketed that would adversely affect the use of the product. Any differences in technological characteristics do not raise new issues of safety or efficacy. Further, testing demonstrates substantially equivalent performance between the device and the predicates. Accordingly, the Endoskeleton® TC is substantially equivalent to the predicate devices in design, function, material, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Titan Spine, LLC
% Hogan & Hartson, LLP
John J. Smith, M.D., J.D.
555 13th Street, NW
Washington, District of Columbia 20004

JUL 2 9 2010

Re: K100889
Trade/Device Name: Endoskeleton® TC
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: June 28, 2010
Received: June 28, 2010

Dear Dr. Smith:

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

K100889

Indications for Use Statement

JUL 25 2010

510(k) Number (if known): K100889

Device Name: Endoskeleton® TC

Indications for Use:

The Endoskeleton® TC is indicated for use for anterior cervical interbody fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from C-3 to C-7. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The Endoskeleton® TC is indicated to be used with supplemental fixation and autograft bone.

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