K102067

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

NOV - 5 2010

Date:	May 28, 2010	
Contact:	Kevin Gemas President 866-822-7800	Titan Spine, LLC Mequon Research Center 6140 Executive Dr., Suite A Mequon, WI 53092
Trade Name:	Endoskeleton TO® Interbody Fusion Device	
Product Class:	Class II	
Classification:	21 CFR §888.3080 Orthosis, intervertebral body fusion device	
Product Codes:	MAX	
Panel Code:	87	

Name of Device and Name/Address of Sponsor
Endoskeleton® TO

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

Common or Usual Name
Intervertebral body fusion device

Predicate Devices
The Endoskeleton® TO was shown to be substantially equivalent to legally marketed predicate devices. The predicate devices include the Ray Threaded Fusion Cage (P950019), the Lumbar I/F Cage (P960025), the Endoskeleton TT Interbody Fusion Device (K083714) and the BAK and BAK Proximity (P950002-S3).

Intended Use / Indications for Use
The Endoskeleton TO® Interbody Fusion Device is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

Technological Characteristics

The Endoskeleton® TO is comprised of a variety of implant sizes to accommodate various patient's anatomy and pathology, and associated instrumentation. All implantable components are manufactured from medical grade titanium alloy (Ti6Al4V-ELI).

Performance Data

Static and dynamic axial compression, static and dynamic compression shear, and static torsion were completed following ASTM F2077-03. Subsidence was tested following ASTM F2267-04. Expulsion testing was conducted following a recognized protocol to allow comparison evaluation of intervertebral body fusion device assemblies, and characterize their resistance to expulsion. The above pre-clinical testing performed on the Endoskeleton TO Interbody Fusion Device indicated that the Endoskeleton TO Interbody Fusion Device is substantially equivalent to the predicate devices and is adequate for the intended use.

Summary:

The Endoskeleton TO Interbody Fusion Device and predicate devices have the same intended use, to provide mechanical stability in the lumbar disc space to facilitate biologic fusion. The indications for use of the Endoskeleton TO Interbody Fusion Device contain no new language that is not already included in at least one of the predicate devices. Moreover, the device is very similar in its size to the predicate devices. The materials used are also the same as in some predicate devices. There are no significant differences in technological characteristics compared to the predicates, and the minor differences that do exist do not raise any new types of safety or efficacy issues. Furthermore, bench testing demonstrates that these differences do not adversely impact device performance, as discussed below.

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

Titan Spine, LLC
% Silver Pine Consulting, LLC
Rich Jansen, Pharm.D.
13540 Guild Avenue
Apple Valley, Minnesota 55124

NOV - 5 2010

Re: K102067
Trade/Device Name: Endoskeleton® TO Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 22, 2010
Received: August 11, 2010

Dear Dr. Jansen:

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 Statement

510(k) Number (if known): K102067

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Device Name: Endoskeleton® TO

Indications for Use:

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Prescription Use ___V____ (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 K102067