FEB 11 2011

510(k) SUMMARY

Submitter's Name:	Bright Spine
Submitter's Address:	799 N.E. 71st Street Boca Raton, Florida 33489
Contact Person:	Robert E. Simonson
Telephone / Facsimile:	Tel: 561-289-9378 Fax: 561-998-5890
Date Prepared:	July 22, 2010
Device Trade Name:	Galileo™ Spinal Spacer System
Device Common Name:	Intervertebral Body Fusion Device
Classification Name:	Orthosis, Spinal Intervertebral Fusion with Bone Graft, Cervical
Classification Number(s)/Product Code(s)	21 CFR 888.3080 (ODP)
Predicate Device:	Alphatec Spine, Inc. Novel® Spinal Spacer System K081730
Device Description:	The Bright Spine Galileo™ Spinal Spacer System is an implantable device manufactured from titanium alloy
Intended Use:	To provide the surgeon with a cervical intervertebral body fusion device, intended for spinal fusion procedures at one level (C2 to TI) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be packed with autogenous bone graft. These patients should have had six months of non-operative treatment. The Galileo™ Spinal Spacer System is to be used with a supplemental fixation system.

Technological Characteristics and Comparison to Predicate:	The Bright Spine Galileo™ Spinal Spacer System is manufactured from equivalent materials, with similar dimensions, to achieve the same surgical objectives as the predicate Novel® Spinal Spacer System.
Performance Data:	When used as designed, the Galileo™ Spinal Spacer System functions in as safe and effective a manner as the predicate device. Complies with ASTM F2077-03 and ASTM F2267-04 Performance Testing. ASTM F2077-03 Includes: Static and dynamic compression, compressive shear, torsion and expulsion ASTM F2267-04 Includes: Subsidence The Galileo™ Spinal Spacer System was shown to be substantially equivalent to the predicate system.
Clinical Data:	It was determined that Clinical Data was not required to determine substantial equivalence.

Conclusion: The Bright Spine Galileo™ Spinal Spacer System is safe and effective and is substantially equivalent to the predicate device.

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

Bright Spine, Inc.
% Mr. Robert E. Simonson
799 N.E. 71st Street
Boca Raton, Florida 33489

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Re: K102449
Trade/Device Name: Bright Spine Galileo™ Spinal Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Invertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: January 10, 2011
Received: January 11, 2011

Dear Mr. Simonson:

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): K102449

Device Name: Bright Spine Galileo™ Spinal Spacer System

Indications for Use:

When used as a Cervical Intervertebral Body Fusion Device

When used as a cervical intervertebral body fusion device, the Galileo™ Spinal Spacer System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the cervical spine. Implants are to be packed with autogenous bone graft. These patients should have had six months of non-operative treatment. The Galileo™ Spinal Spacer System is to be used with a supplemental fixation system.

Prescription Use __X_____ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K102449