Eminent Spine Interbody Fusion System

APR - 9 2009

Premarket Notification

SUBMITTED BY	Eminent Spine 16001 Ronald Reagan Blvd Leander, TX 78641
ESTABLISHMENT REGISTRATION NUMBER	Pending
OWNER/OPERATOR NUMBER	10028153
CONTACT PERSON	**Primary** Dave Freehill President/Co-Founder Phone: 512-259-9002 Fax: 512-259-9515 **Alternate** Steve Courtney, M.D. President/Co-Founder Phone: 214-415-5243 Fax: 972-250-5651
SUBMISSION PREPARED BY	Lisa Peterson QA Consulting, Inc. Phone: 512-507-0746
DATE PREPARED	January 6, 2009
CLASSIFICATION NAME	MAX 888.3080- Intervertebral Fusion Device with Bone Graft, Lumbar ODP 888.3080 - Intervertebral Fusion Device with Bone Graft, Cervical MQP 888.3060 - Spinal Intervertebral Body Fixation Orthosis
COMMON NAME	Intervertebral Body Fusion Device (MAX, ODP) Spinal Vertebral Body Replacement Device (MQP)
PROPRIETARY NAME	Eminent Spine Interbody Fusion System
PREDICATE DEVICE(S)	Predicate devices include several recently down classified cages, as well as various cleared interbody fusion/VBR systems: - LT-CAGE® Peek Lumbar Tapered Fusion Device (P970015, Medtronic Sofamor Danek, Approved 9/10/03) - BAK® Cage (P950002, Zimmer Spine, Approved 7/8/03) - RAY® Threaded Fusion Cage (P950019, Stryker, Approved 9/4/03) - Lumbar I/F Cage (P960025, DePuy, Approved 3/4/05) - BAK/C (P980048, Zimmer Spine, Approved 4/20/01) - Affinity Cage System (P000028, Medtronic, Approved 6/13/02) - Zeus Cages (K081614, Interbody Innovations, Cleared 9/5/08) - MC+ Partial VBR (K043479, LDR Spine, Cleared 6/30/05) - Crystal (K073351, Spinal Elements, Inc., Cleared 1/24/08)

SUBSTANTIAL EQUIVALENCE

The Eminent Spine Interbody Fusion System was determined to be substantially equivalent to several commercially available systems.

DEVICE DESCRIPTION

The Eminent Spine Interbody Fusion System is comprised of various sizes and configurations to accommodate individual patient anatomy. The configurations are designed to provide the surgeon with different surgical approach options.

The Eminent Spine Interbody Fusion System will be offered in four (4) configurations of various sizes. The configurations are designed based on indicated spinal implant level and surgical approach, and consist of: 1) Copperhead, anterior cervical approach 2) Sidewinder, transforaminal lumbar approach 3) Python, posterior lumbar approach and 4) Cottonmouth, anterior lumbar approach.

INDICATIONS:

Intervertebral Body Fusion Device:
The Eminent Spine Interbody Fusion System (Sidewinder, Python and Cottonmouth) is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

The Eminent Spine Interbody Fusion System (Copperhead) is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level from the C2-C3 disc to the C7-TI disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Vertebral Body Replacement Device:
The Eminent Spine System of implants is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The Eminent Spine System is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. These devices are intended to be used with autograft or allograft bone.

MECHANICAL TEST DATA

Mechanical test results demonstrate that the proposed Eminent Spine Interbody Fusion System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Eminent Spine
% Mr. Dave Freehill
President
16001 Ronald Reagan Boulevard
Leander, Texas 78641

APR - 9 2009

Re: K090064
Trade/Device Name: Eminent Spine Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP, MQP
Dated: January 6, 2009
Received: January 9, 2009

Dear Mr. Freehill:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: **Eminent Spine Interbody Fusion System**

Indications for Use:

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for MKM
Division of General, Restorative, and Neurological Devices

510(k) Number K090064