K090048

AUG 14 2009

2. 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with 21 CFR 807.92

General Information:

A. Submitted By:

Medical Designs, LLC.
1210 W. 18th Street, Suite 104
Sioux Falls, South Dakota 57104
Tel: 605-275-1032
Fax: 605-335-3734

Contact Person: Kristi Vondra, Vice President of Operations

Date Prepared: August 12, 2009

B. Device Trade Name: Asfora Bullet Cage™

Classification Name: Orthopedic Devices, Prosthetic Devices
Intervertebral Fusion Device with Bone Graft, Lumbar
21 CFR 888.3080 (MAX)

C. Predicate Devices: INTER FIX™ Threaded Fusion Device (P970013; Downclassified to Class II)

Ray TFC™ Device (P950019; Downclassified to Class II)

D. Device Description:

The Asfora Bullet Cage™ is comprised of two hollow, threaded, self-tapping titanium fusion devices (cages) with closed tapered medial ends. The distal end has a small orifice that can be closed with a threaded cap. There are six equidistant slit apertures along the longitudinal axis of the device for placement of autogenous bone graft material. The cage has large cutting threads, angled toward the proximal end.

The Asfora Bullet Cage™ is available in ten sizes: 5 diameters (10mm, 12mm, 14mm, 16mm, and 18mm) and 2 lengths (21mm or 25mm). This device, with associated instrumentation is intended for use in posterior lumbar interbody fusion to immobilize adjacent vertebrae and promote arthrodesis (fusion) across the disc space.

E. Indications for Use:

The Asfora Bullet Cage™ (ABC) is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) and instability in the lumbar spine at

one or two levels from L2 to S1. The DDD patients may also have up to Grade I spondylolisthesis at the involved level. The ABC cage devices are used with autogenous bone graft and are implanted via an open posterior approach. Patients should have had at least six (6) months of non-operative treatment prior to implant.

F. Substantial Equivalence Comparison of Technical Characteristics to Predicate Device(s):

The clinical and performance data provide adequate information to demonstrate that the Asfora Bullet Cage™ and its predicates, the INTER FIX™ Threaded Fusion Device (P970013; Downclassified to Class II) and the Ray RFC™ Device (P950019; Downclassified to Class II) are substantially equivalent.

H. Summary:

Testing and comparison of technological characteristics and intended uses found that all components of the Asfora Bullet Cage™ are equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Medical Designs, LLC
% Kristi Vondra
1210 W 18th St. North Center, Suite 104
Sioux Falls, South Dakota 57104

AUG 14 2009

Re: K090048
Trade/Device Name: Asfora Bullet Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 12, 2009
Received: August 13, 2009

Dear Ms. Vondra:

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.

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 (240) 276-3150 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): K090048

Device Name: The Asfora Bullet Cage™

Indications for Use:

The Asfora Bullet Cage™ (ABC) is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) and instability in the lumbar spine at one or two levels from L2 to S1. The DDD patients may also have up to Grade I spondylolisthesis at the involved level. The ABC cage devices are used with autogenous bone graft and are implanted via an open posterior approach. Patients should have had at least six (6) months of non-operative treatment prior to implant.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(EXT for MXM)

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

510(k) Number K090048