Medical Designs, LLC
Kristi Vondra
VP of Operations
6709 S. Minnesota Ave, Suite 204
Sioux Falls, South Dakota 57108

September 26, 2018

Re: K181591
Trade/Device Name: Fixated Asfora BULLET CAGE® (FABC)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, OVD
Dated: August 15, 2018
Received: August 17, 2018

Dear Kristi 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181591

Device Name
Fixated Asfora BULLET CAGE® (FABC)

Indications for Use *(Describe)*
The Fixated Asfora BULLET CAGE® (FABC) is indicated for spinal fusion procedures in skeletally mature patients for the treatment of degenerative disc disease (DDD) and instability in the lumbar spine at one or two contiguous levels from L2 to S1. DDD for lumbar systems is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). Patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The FABC devices are used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

When used with the two fixation screws, the FABC System is a stand-alone system and requires no additional supplemental fixation. When used without the fixation screws, the FABC System should be used with supplemental fixation cleared for use in the lumbar spine. When only one device is implanted, the FABC System must be used with supplemental fixation cleared for use in the lumbar spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Date:	5 Sept 2018
Sponsor:	Medical Designs, LLC 6709 South Minnesota Avenue, Suite 204 Sioux Falls, SD 57108 Office: 888.276.7271 Fax: 605.335.3734
Sponsor Contact:	Kristi Vondra, VP of Operations
Proposed Trade Name:	Fixated Asfora BULLET CAGE® (FABC)
Common Name:	Lumbar interbody fusion system with and without fixation
Device Classification:	Class II
Regulation Name, Regulation Number, Product Codes:	Intervertebral body fusion device, 888.3080, MAX & OVD
Device Description:	The Fixated Asfora BULLET CAGE® (FABC) System is comprised of a threaded titanium alloy interbody fusion cage and two optional fixation screws. The implants are available in an assortment of diameter and length combinations to accommodate a variety of anatomic requirements. The instrumentation for implantation is manufactured from medical grades of stainless steel per ASTM F899 with some having silicone handles.
Indications for Use:	The Fixated Asfora BULLET CAGE® (FABC) is indicated for spinal fusion procedures in skeletally mature patients for the treatment of degenerative disc disease (DDD) and instability in the lumbar spine at one or two contiguous levels from L2 to S1. DDD for lumbar systems is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). Patients should be skeletally mature and have had at least six (6) months of non-operative treatment. The FABC devices are used with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft. When used with the two fixation screws, the FABC System is a stand-alone system and requires no additional supplemental fixation. When used without the fixation screws, the FABC System should be used with supplemental fixation cleared for use in the lumbar spine. When only one device is implanted, the FABC System must be used with supplemental fixation cleared for use in the lumbar spine.
Materials:	FABC System implants are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F136).
Primary Predicate:	Primary: S128 Anterior Lumbar Interbody Fusion (ALIF) System (Renovis Surgical Technologies, Inc. – K140106)
Additional Predicates:	Avenue® L Lateral Lumbar Cage and Avenue® T Posterior Lumbar Cage (LDR Holding [now Zimmer Biomet] – K153495), Asfora BULLET CAGE® ABC (Medical Designs – K090048, K112648), STALIF (Centinel Spine, Inc. – K101301), MC+ (LDR Holding – K043479), SynCage-C (Synthes Spine – K024364), Lumbar I/F Cage® (DePuy AcroMed, Inc. – P960025) and AVS® ARIA PEEK Spacers (Stryker Corporation – K143163), TM Ardis® Interbody System (Zimmer Trabecular Metal Technology, Inc. – K113561).
Reference Devices:	ASFORA ANTERIOR CERVICAL PLATE SYSTEM (Medical Designs – K143688)

Performance Data:

Mechanical testing of worst case FABC System devices included static and dynamic compression, static and dynamic compression shear and static torsion according to ASTM F2077. In addition, the subsidence properties were evaluated according to ASTM F2267 and expulsion according to the ASTM draft standard.

The mechanical test results demonstrate that FABC System performance is substantially equivalent to the predicate devices.

Technological Characteristics:

The FABC System possesses the same technological characteristics as one or more of the predicate devices. These include:

- intended use (as described above)
- basic design (cage with integrated fixation),
- material (titanium alloy) and
- sizes (dimensions are comparable to those offered by the predicate systems).

While the FABC System is not identical to the predicate devices, the differences were shown not to raise new questions of safety and effectiveness. Therefore the fundamental scientific technology of the FABC System is similar to previously cleared devices.

Conclusion:

The FABC System possesses the same intended use and technological characteristics as the predicate devices. Therefore the FABC System is substantially equivalent for its intended use.