FEB 25 2010

V. 510(K) SUMMARY

Binder Biomedical, Inc.'s Intervertebral Body Fusion Device

Submitted by:

Binder Biomedical, Inc.
2385 NW Executive Center Dr, Suite 100
Boca Raton, FL 33431
Phone: (561) 981-2682
Facsimile: (561) 962-2710
Contact Person: Lawrence Binder

Date Prepared: September 27, 2009

Device Name and Address of Sponsor

Binder Intervertebral Body Fusion Device
Binder Biomedical, Inc.
2385 NW Executive Center Dr, Suite 100
Boca Raton, FL 33431

Common Name

Intervertebral Body Fusion Device

Classification

Orthosis, Spinal Intervertebral Fusion

Predicate Devices

DePuy AcroMed, Inc.	Lumbar I/F Cage with VSP Spine System
Globus Medical, Inc.	PATRIOT Spacers
Lanx, Inc.	Lanx Intervertebral Body Fusion Device

Intended Use / Indications for Use

The Binder Intervertebral Body Fusion Device ("Binder Fusion System") is intended to be used for intervertebral body fusion.

The Binder Intervertebral Body Fusion Device is indicated for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous levels of the lumbosacral spine (L2-S1). DDD is

defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have had a previous non-fusion spinal surgery at the involved level(s) and may have had up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Binder Fusion devices are to be used with autogenous bone graft material and supplemental fixation.

Technological Characteristics

The Binder Fusion System is comprised of a series of PEEK-OPTIMA® spacers shaped to accommodate autogenous bone graft and anatomical variation at different spinal levels. The Binder Fusion System also has a series of ridges on its superior and inferior surfaces to improve fixation and prevent migration. The Binder Fusion System is provided non-sterile.

Performance Data

Performance testing was conducted per ASTM F2077-03 and ASTM F2267-04. In all instances, the Binder Fusion System functioned as intended and specified requirements were met.

Basis of Substantial Equivalence

The Binder Fusion System is as safe and effective as the predicate devices. The Binder Fusion System has the same intended uses, indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the Binder Fusion System and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Binder Fusion System is as safe and effective as the predicate devices. Thus, the Binder Fusion System is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 2 5 2010

Binder Biomedical, Inc.
% Mr. Lawrence Binder
President and CEO
2385 NW Executive Center Drive
Suite 100
Boca Raton, Florida 33431

Re: K093015
Trade/Device Name: Binder Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 17, 2010
Received: February 19, 2010

Dear Mr. Binder:

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,

Barbara Buehrn
for

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

Enclosure

IV. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093015

Device Name: Binder Intervertebral Body Fusion Device

Indications for Use:

The Binder Intervertebral Body Fusion Device ("Binder Fusion System") is indicated for use in patients with degenerative disc disease (DDD) at one (1) or two (2) contiguous levels of the lumbosacral spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have had a previous non-fusion spinal surgery at the involved level(s) and may have had up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Binder Fusion devices are to be used with autogenous bone graft material and supplemental fixation.

Prescription Use ____X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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 K093015