SEP 1 3 2013

5. 510(K) SUMMARY

Submitter's Name:	Binder Biomedical, Inc.
Submitter's Address:	1951 NW 7th Avenue, Suite 13135 Miami, FL 33136
Submitter's Telephone:	561.981.2682
Contact Name:	Lawrence Binder
Date Summary was Prepared:	06 March 2013
Trade or Proprietary Name:	LOGIC Stand-Alone Intervertebral Body Fusion Device
Common or Usual Name:	Lumbar stand-alone intervertebral body fusion device
Classification:	Class II per 21 CFR §888.3080
Product Code:	OVD
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate Devices:	Biomet Solitaire PEEK Anterior Spinal System (K081395 & K120557) Binder Intervertebral Body Fusion Device (K093015) Synthes Synfix-LR system (K072253) Centinel Spine STALIF system (K073109)

DESCRIPTION OF THE DEVICE

The LOGIC system consists of a PEEK spacer with titanium bone screws for intervertebral body fusion. Screws are available in a variety of diameter-length combinations. Spacers are available in a variety of widths, depths, and heights. Fixation is achieved by inserting bone screws through the openings in the spacer into the vertebral bodies of the lumbar spine. The screws are intended to be used as integrated fixation for stand-alone use of the device.

INDICATIONS FOR USE

The LOGIC Stand-Alone Intervertebral Body Fusion Device is indicated for stand-alone intervertebral body fusion 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 I spondylolisthesis or retrolisthesis at the involved level(s).

The LOGIC Stand-Alone Intervertebral Body Fusion Device is to be used with autogenous bone graft material.

TECHNICAL CHARACTERISTICS

The device is manufactured from PEEK-OPTIMA® (ASTM F2026, ISO 10993) with tantalum (ASTM F560-08) markers. Both materials have a successful history of use in the spinal implant industry and use of it in these devices does not introduce any previously unaccepted patient risks. The predicate devices are manufactured from PEEK-OPTIMA® and titanium alloy along with tantalum markers. All referenced predicates are also manufactured from PEEK-OPTIMA®.

The bone screws are manufactured from titanium alloy meeting requirements of ASTM F136-11, *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* Titanium alloy has a successful history of use in the spinal implant industry and use of it in these devices does not introduce any previously unaccepted patient risks. The predicate bone screws are also manufactured from titanium alloy.

PERFORMANCE DATA

The LOGIC system has been tested in the following test modes:

- Static and dynamic axial compression per ASTM F2077-11
- Static and dynamic compressive shear per ASTM F2077-11
- Static Subsidence per ASTM F2267-04
- Static Expulsion per ASTM Draft Standard F-04.25.02.02, "Static Push-out Test Method for Intervertebral Body Fusion Devices." Draft #2 – August 29, 2000

The results of this non-clinical testing show that the LOGIC device is substantially equivalent to the predicate devices.

SUBSTANTIAL EQUIVALENCE

The LOGIC device is substantially equivalent to its predicates for intervertebral body fusion in regards to intended use, design, materials, processing, and operational principles. Based upon the overall technology characteristics and mechanical performance data, it is has been established that the LOGIC Stand Alone Intervertebral Body Fusion Device is substantially equivalent to the predicate devices currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 13, 2013

Binder Biomedical, Incorporated
Mr. Lawrence Binder
President and CEO
1951 Northwest 7th Avenue, Suite 13135
Miami, Florida 33136

Re: K130641
Trade/Device Name: LOGIC Stand-Alone Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: July 26, 2013
Received: August 12, 2013

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 contact 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. 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 -S

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

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number if known: K130641

Device Name: LOGIC Stand-Alone Intervertebral Body Fusion Device

The LOGIC Stand-Alone Intervertebral Body Fusion Device is indicated for stand-alone intervertebral body fusion 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 I spondylolisthesis or retrolisthesis at the involved level(s).

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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)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices