

K111122

B, 510(k) SUMMARY (as required by 21 CFR 807.92)

AUG - 4 2011

Aesculap® Implant Systems(AIS) – SIBD XP Spinal System
August 1, 2011

COMPANY: Aesculap® Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Lisa M. Boyle
610-984-9274 (phone)
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TRADE NAME: AIS SIBD XP Spinal System

COMMON NAME: Intervertebral Body Fusion Device

CLASSIFICATION NAME: Intervertebral Fusion Device with Integrated Fixation,
Lumbar

REGULATION NUMBER: 888.3080

PRODUCT CODE: OVD

PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the AIS SIBD XP Spinal System.

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems, Inc. believes that the AIS SIBD XP Spinal System is substantially equivalent to the design of the AIS SIBD Spinal System (K100802). The Plasmapore® coating used for the subject device is similar to the the Plasmapore® coating of the AIS Hydrolift VBR System (K083186). Furthermore, the coating has been used and cleared in a number of legally marketed systems in the US and Europe for many years.

DEVICE DESCRIPTION

The AIS SIBD XP Spinal System is an implantable spinal device manufactured from PEEK-OPTIMA® LT (Polyetheretherketone) per ASTM F2026, with a titanium layer and a vacuum plasma spray coating (Plasmapore®). The device will have Tantalum markers per ASTM F-560. The implant is secured to vertebral bodies by four titanium screws inserted through the anterior screw holes. The implants are offered in a variety of shapes and sizes to meet the requirements of the individual patient anatomy.

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INDICATIONS FOR USE

The AIS SIBD XP Spinal System is a stand-alone device intended to be used with the four supplied bone screws if no supplemental fixation is used.

As an intervertebral body fusion device designed for use with autograft, the SIBD XP Spinal System is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s).

Patients should be skeletally mature and must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Aesculap® Implant Systems device.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the SIBD XP Spinal System are offered in the same range of shapes and sizes as the predicate device. The material used for the Aesculap® Implant Systems device is the same as that used to manufacture the predicate devices. The only difference between the predicate device and the subject device is the titanium layer and a vacuum plasma spray coating (Plasmapore®).

PERFORMANCE DATA

As recommended by the FDA Guidance for Spinal System 510(k)'s, non-clinical testing was performed to demonstrate that the AIS SIBD XP Spinal System is substantially equivalent to other predicate devices. The following testing was performed:

- Static and dynamic torsion per ASTM F2077
- Static and dynamic axial compression per ASTM F2077
- Static and dynamic shear compression testing per ASTM F2077
- Subsidence per ASTM F2267
- Wear Debris per ASTM F2077 & ASTM F1877
- Expulsion per ASTM Draft Standard F-04.25.02.02

In addition to FDA's Spine Guidance, Aesculap has also completed non-clinical testing recommended in the "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements." The following tests were performed:

- Microstructure of the coating per ASTM F1854
- Static Tensile Strength per ASTM F1147
- Static Shear Strength per ASTM F1044

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- Shear Fatigue Test per ASTM F1160
- Abrasion Resistance per ASTM F1978

The results of these tests showed that the AIS SIBD XP Spinal System meets or exceeds the performance of the predicate devices, and the device is therefore found to be substantially equivalent.



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

Aesculap Implant Systems, Inc.
% Ms. Lisa M. Boyle
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

AUG - 4 2011

Re: K111122

Trade/Device Name: Aesculap® Implant Systems (AIS) – SIBD XP Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: July 08, 2011
Received: July 11, 2011

Dear Ms. Boyle:

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

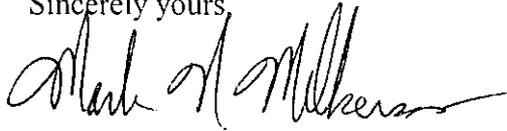
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing 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" (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 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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

