JAN 2 2 2014

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

Aesculap® Implant Systems(AIS) – Plasmapore® XP Spinal Implant System

December 18, 2013

COMPANY: Aesculap®Implant Systems (AIS), LLC.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

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TRADE NAME: AIS Plasmapore® XP Spinal Implant System
COMMON NAME: Intervertebral Fusion Device Device
CLASSIFICATION NAME: Orthosis, Spinal Intervertebral Fusion
REGULATION NUMBER: 888.3080
PRODUCT CODE: MAX
REVIEW PANEL: Orthopedics

PURPOSE FOR PREMARKET SUBMISSION

The AIS Plasmapore® XP Spinal Implant System described in this submission is for modifications made to the PEEK Prospace implant and for the addition of a Plasmapore® coating to the existing ProSpace PEEK Intervertebral Body Fusion implants cleared under K071983.

INDICATIONS FOR USE

When used as an Intervertebral Body Fusion System:

The Plasmapore® XP Spinal Implant System is indicated for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at involved levels. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s). The Plasmapore® XP Spinal Implant System is intended for use with supplemental spinal fixation systems that have been cleared for use in the lumbrosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The Plasmapore® XP Spinal Implant System can be used individually or in pairs. The Plasmapore® XP Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

DEVICE DESCRIPTION

The Plasmapore® XP Spinal Implant System is an intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. Components are offered in a variety of shapes and sizes to meet the requirements of the individual patient anatomy. Components are manufactured from PEEK – Optima (per ASTM F2026) with a titanium layer and a vacuum plasma spray coating (Plasmapore® - per ISO 5832-3). The device will have titanium alloy (TiAl6V4) radiographic markers per ISO 5832-3.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the Plasmapore® XP Spinal Implant 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 ProSpace XP implant is substantially equivalent to other predicate devices. The following testing was performed:

- Static torsion per ASTM F2077
- Static and dynamic axial compression per ASTM F2077
- Shear resistance evaluation per ASTM F2267
- Subsidence per ASTM F2267
- Wear Debris Analysis per ASTM F1877

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

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

SUBSTANTIAL EQUIVALENCE

AIS believes that the Plasmapore® XP Spinal Implant System is substantially equivalent to the design of the AIS PEEK VBR and Intervertebral Body Fusion Systems (K071983). The Plasmapore® coating has been used and cleared in a number of legally marketed product lines manufactured by Aesculap (hip, knee, and spinal implants) for many years. The most recent Spinal Implant to be cleared with the Plasmapore® coating is the CeSpace XP Intervertebral Body Fusion Device (K123909).

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

January 22, 2014

Aesculap Implant Systems, Incorporated
Ms. Lisa M. Boyle
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K132421
Trade/Device Name: AIS Plasmapore® XP Spinal Implant System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 19, 2013
Received: December 20, 2013

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 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" (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,

Lori A. Wiggins

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132421

Device Name
Plasmapore® XP Spinal Implant System

Indications for Use *(Describe)*

The Plasmapore® XP Spinal Implant System are indicated for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at involved levels. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s). The Plasmapore® XP Spinal Implant System is intended for use with supplemental spinal fixation systems that have been cleared for use in the lumbrosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems). The Plasmapore® XP Spinal Implant System implants can be used individually or in pairs. The Plasmapore® XP Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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