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

Aesculap Implant Systems, LLC
Ms. Lisa M. Boyle
Regulatory Affairs Manager
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

August 13, 2015

Re: K151056
Trade/Device Name: Aesculap T-Space PEEK and XP Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: July 16, 2015
Received: July 17, 2015

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 Industry and Consumer Education 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 Industry and Consumer Education 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

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)*
K151056

Device Name
Aesculap T-Space PEEK and XP Spinal System

Indications for Use *(Describe)*

When used as an Intervertebral Body Fusion System:
The T-Space 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 AIS T-Space 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 AIS T-Space Spinal Implant System implants can be used individually or in pairs. The AIS T-Space 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 Aesculap 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)*

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

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Aesculap® Implant Systems(AIS) – T-Space Spinal Implant System

August 10, 2015

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

CONTACT: Lisa M. Boyle, Regulatory Affairs Manager
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610-791-6882 (fax)
lisa.boyle@aesculap.com

TRADE NAME: Aesculap T-Space PEEK and XP Spinal System
COMMON NAME: Intervertebral Fusion Device
CLASSIFICATION NAME: Orthosis, Spinal Intervertebral Fusion
REGULATION NUMBER: 21 CFR 888.3080
PRODUCT CODE: MAX
REVIEW PANEL: Orthopedics

INDICATIONS FOR USE

When used as an Intervertebral Body Fusion System:
The T-Space 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 AIS T-Space 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 AIS T-Space Spinal Implant System implants can be used individually or in pairs. The AIS T-Space 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 Aesculap device.

DEVICE DESCRIPTION

The T-Space 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. The implants are offered in a coated and uncoated version and a variety of shapes and sizes to meet the requirements of the individual patient anatomy. The uncoated PEEK version is manufactured from PEEK – Optima (per ASTM F2026). The coated version will be the same in design as the uncoated PEEK implant with a titanium layer and a vacuum plasma spray coating (Plasmapore® - per ISO 5832-3). The device will have tantalum radiographic markers per ASTM F-560.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the T-Space Spinal Implant System are offered in the same similar shapes and sizes as the predicate devices. The material used for the Aesculap® Implant Systems device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

As recommended by the FDA Guidance for Spinal System 510(k)'s, non-clinical testing was performed to demonstrate that the AIS T-Space implants (coated and uncoated) are 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

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 T-Space 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 T-Space Spinal Implant System is substantially equivalent to the design of the Spinal Elements Lucent System (K122967) and 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 Implants to be cleared with the Plasmapore® coating is the CeSpace XP Intervertebral Body Fusion Device (K123909) and ProSpace XP Intervertebral Body Fusion Device (K132421).

PRIMARY PREDICATES:

- Spinal Elements Lucent System (K122967)

ADDITIONAL PREDICATES:

- AIS PEEK VBR and Intervertebral Body Fusion Systems (K060762 / K071983).
- CeSpace XP Intervertebral Body Fusion Device (K123909) and,
- ProSpace XP Intervertebral Body Fusion Device (K132421).