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

May 25, 2016

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

Re: K153629
Trade/Device Name: Arcadius^{XP} C Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: April 25, 2016
Received: April 26, 2016

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 Parts 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 below.

510(k) Number *(if known)*
K153629

Device Name
ArcadiusXP C Spinal System

Indications for Use *(Describe)*

The ArcadiusXP C Spinal System is intended to be used as an intervertebral body fusion device as a standalone system used with the supplied bone screws and requires no additional supplementary fixation system. It is intended for spinal fusion procedures at one level in the cervical spine from the C2/C3 disc space to the C7/Tl disc space for the treatment of cervical degenerative disc disease (defined as discogenic pain with degeneration ofthe disc confirmed by history and radiographic studies) using autograft bone.

Patients should be skeletally mature and must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the ArcadiusXP C Spinal System.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

Aesculap® Implant Systems (AIS) – Arcadius^{XP} C *Spinal System*

May 18, 2016

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

CONTACT: Lisa M. Boyle
610-984-9274 (phone)
610-791-6882 (fax)

TRADE NAME: Arcadius^{XP} C Spinal System

COMMON NAME: Intervertebral Body Fusion Device

CLASSIFICATION NAME: Intervertebral Fusion Device with Integrated Fixation, Cervical

REGULATION NUMBER: 888.3080

PRODUCT CODE: OVE

PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the Arcadius^{XP} C Spinal System.

DEVICE DESCRIPTION

The Arcadius^{XP} C spinal system is a stand-alone cervical interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy procedures. The system consists of a PEEK cage and two bone screws. The PEEK cages are manufactured from a radiolucent material medical grade LT1 polyetheretherketone (PEEK) per ASTM F2026, with a titanium layer and a vacuum titanium plasma spray coating (PlasmaporeXP). The Arcadius^{XP} C implants are offered in various heights and geometrical options to fit the anatomical needs of a wide variety of patients. The Arcadius^{XP} C implant is available in two footprints. The wide central opening holds optimal graft material. The screws are 4mm in diameter and offered in three lengths. The fixation screws and radiographic markers are manufactured of titanium alloy, (Ti6Al4V) according to ISO 5832/3.

INDICATIONS FOR USE

The Arcadius^{XP} C Spinal System is intended to be used as an intervertebral body fusion device as a standalone system used with the supplied bone screws and requires no additional supplementary fixation system. It is intended for spinal fusion procedures at one level in the cervical spine from the C2/C3 disc space to the C7/T1 disc space for the treatment of cervical degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies) using autograft bone.

Patients should be skeletally mature and must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Arcadius^{XP} C Spinal System.

SUBSTANTIAL EQUIVALENCE

The Arcadius^{XP} C Spinal System is substantially equivalent to the predicates in design, material, function and performance. Based on test results and additional supporting documentation provided, Aesculap believes that the subject device demonstrates substantial equivalence.

PERFORMANCE DATA

As recommended by the FDA Class II Special Controls Guidance Document: Intervertebral Body Fusion Device non-clinical testing was performed to demonstrate that the AIS Arcadius^{XP} C 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 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 Post-market 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 Arcadius^{XP} C Spinal System meets or exceeds the performance of the predicate devices, and the device is therefore found to be substantially equivalent.

PRIMARY PREDICATE

Elite Surgical Supplies: Biolign Stand Alone Cervical Cage (STACC) ACIF System – K130274

REFERENCE DEVICES

Centinel Spine: Stalif C® – K150053 / K142079
Aesculap Implant Systems: SIBD XP Spinal System – K111122