



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

October 21, 2015

Re: K151938

Trade/Device Name: S4 Cervical Spinal and Occiput Systems
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: September 21, 2015
Received: September 22, 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.

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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" (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 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

Indications for Use

510(k) Number (if known)

K151938

Device Name

S4 Cervical Spinal and Occiput Systems

Indications for Use (Describe)

The Aesculap S4 Cervical Spinal and Occiput Systems are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Aesculap S4 Cervical Spinal and Occiput Systems are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Aesculap S4 Lumbar System may be connected to the Aesculap S4 Cervical Spinal and Occiput Systems using connectors and rods.

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.

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

***Aesculap® Implant Systems (AIS), LLC.
S4 Cervical Spinal and Occiput Systems***

September 21, 2015

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

CONTACT: Lisa M. Boyle
800-258-1946 (phone)
610-791-6882 (fax)

TRADE NAME: S4 Cervical Spinal and Occiput Systems

COMMON NAME: Posterior, Cervical Pedicle Screw Spine Fixation, Spinal Interlaminar Fixation Orthosis, Posterior Cervical System

CLASSIFICATION NAME: Posterior, Cervical Pedicle Screw Spine Fixation
Orthopaedic and Rehabilitation Devices Panel
Unclassified; Pre-Amendment Device
Product Code: NKG

Appliance, Fixation, Spinal Interlaminar
Orthopaedic and Rehabilitation Devices Panel
Class 2 per 21 CFR 888.3050
Product Code: KWP

PURPOSE FOR PREMARKET NOTIFICATION

The Aesculap S4 Cervical Spinal and Occiput Systems described in this submission represent an expanded indication for the entire S4 Cervical System, including the Aesculap S4C Spinal System cleared under K050979, the Aesculap S4C Spinal System (Additional lengths polyaxial screws) cleared under K060152, the Aesculap S4C Spinal System: Occiput Plate cleared under K062012, the Aesculap S4C Spinal System (Modification to Cross Connector & Add. Smooth Shank Screws) cleared under K062327, and the Aesculap S4C Mini-Occiput Spinal System cleared under K100147.

DEVICE DESCRIPTION

The Aesculap S4 Cervical Spinal and Occiput Systems are implant systems used to facilitate the biological process of spinal fusion. This system is intended to promote

fusion of the cervical and thoracic spine (C1-T3) and occipito-cervico-thoracic junction (occiput-T3). The Aesculap S4 Cervical Spinal and Occiput Systems consist of plates, bone screws, rods, hooks, and connectors. This consists of 3.5mm rod, thin and thick lamina hooks, 3.5 and 4.0mm polyaxial screws of various lengths and cross connectors. The occipital plate is fixed to the occiput with bone screws and the transition by a locking mechanism. The end of the construct is stabilized with polyaxial screws to the upper thoracic spine, as required. The components are available in a variety of lengths in order to accommodate patient anatomy. The Aesculap S4 Cervical Spinal and Occiput Systems are manufactured from Titanium/Titanium alloy and will be provided non-sterile.

INDICATIONS FOR USE

The Aesculap S4 Cervical Spinal and Occiput Systems are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1-T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Aesculap S4 Cervical Spinal and Occiput Systems are also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the Aesculap S4 Lumbar System may be connected to the Aesculap S4 Cervical Spinal and Occiput Systems using connectors and rods.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicates)

As is established in this submission, the Aesculap S4 Cervical Spinal and Occiput Systems are substantially equivalent to other predicate devices cleared by FDA. The subject device is shown to be substantially equivalent and has the same technological characteristics to its predicate devices through comparison in design, intended use, material composition, function and range of sizes.

PERFORMANCE DATA

Published literature and Non-clinical testing demonstrate that the Aesculap S4 Cervical Spinal and Occiput Systems are substantially equivalent to other predicate devices.

The following testing was performed:

- Static Torsion Bending per ASTM F1717-04 and ASTM Work Item 455-Z9592Z (Test No. V684-A)

- Dynamic Torsion Testing per ASTM F1717-04 and ASTM Work Item 455-Z9592Z (Test No. V809)
- Dynamic Compression Testing per ASTM F1717-04 and ASTM Work Item 455-Z9592Z (Test No. V697)
- Static Compression Bending per ASTM F1717-04 and ASTM Work Item 455-Z9592Z (Test No. V683-A)

The results showed that the subject Aesculap S4 Cervical Spinal and Occiput Systems meet or exceed the performance of the predicate devices, and the device is therefore found to be substantially equivalent.

PREDICATE DEVICE

- Synapse Occipital-Cervical-Thoracic (OCT) System (K142838)

REFERENCE DEVICES

- Aesculap S4C Spinal System (K050979)
- Aesculap S4C Spinal System (Additional lengths polyaxial screws) (K060152)
- Aesculap S4C Spinal System: Occiput Plate (K062012)
- Aesculap S4C Spinal System (Modification to Cross Connector & Add. Smooth Shank Screws) (K062327)
- Aesculap S4C Mini-Occiput Spinal System (K100147)