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

MAR 1 2 2013

S4 Spinal System
March 11, 2013

COMPANY: Aesculap®Implant Systems (AIS), LLC.
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 S4 Spinal System
COMMON NAME: Pedicle Screw System

REGULATION NUMBER: 888.3070 – Orthosis, Spinal Pedicle Fixation For Degenerative Disc Disease
888.3070 – Orthosis, Spinal Pedicle Fixation
888.3070 - Orthosis, Spondyloisthesis Spinal Fixation
888.3050 – Appliance, Fixation, Spinal Fixation

PRODUCT CODE: NKB, MNI, MNH, and KWP
REVIEW PANEL: Orthopedics

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems (AIS), LLC., believes that the new components of the S4 Spinal System are substantially equivalent in design to the components that are previously cleared in the MACS TL System (K002824) and the S4 Spinal Systems (K032219/K100623).

DEVICE DESCRIPTION

The S4 Spinal System consists of polyaxial screws and monoaxial screws of varying diameters and lengths, staples, various hook styles, rods of varying lengths, fixed and adjustable cross-connectors, and various styles of rod connectors. All implant components are top loading and top tightening. The S4 Spinal System is manufactured from Titanium and Titanium alloy in accordance with ISO 5832/3 and ISO 5832/2.

INDICATIONS FOR USE

The S4 Spinal System is intended for anterior/anterolateral and posterior, non-cervical pedicle and non-pedicle fixation. Fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for treatment of the following acute and chronic instabilities or deformities:

1) degenerative disc disease (defined as discogenic back pain with

degeneration of the disc confirmed by history and radiographic studies)
2) spondylolisthesis,
3) trauma (i.e., fracture or dislocation),
4) spinal stenosis,
5) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6) tumor,
7) pseudoarthrosis, and
8) failed previous fusion.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The new components of the Aesculap® Implant Systems (AIS) S4 Spinal System are offered in similar shapes and sizes as the predicate devices. All the components are manufactured from Titanium and Titanium Alloy, which is the same material as 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 S4 Staples are substantially equivalent to other predicate devices. The following testing was performed:

- Static Axial Compression per ASTM 1717-12
- Dynamic Axial Compression per ASTM F1717-12
- Static Torsion per ASTM 1717-12

The results of these studies showed that the subject S4 Staples meet or exceed the performance of the predicate devices, and the device is therefore found to be substantially equivalent.

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
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Letter dated: March 12, 2013

Re: K123939
Trade/Device Name: S4 Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: December 19, 2012
Received: December 20, 2012

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 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" (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 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 -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K123939

Device Name: S4 Spinal System

Indications for Use:

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6) tumor,
7) pseudoarthrosis, and
8) failed previous fusion.

Prescription Use __X__ and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123939