JUL 23 2010

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

S4 Cervical Occipital Plate Spinal System
January 18, 2010

COMPANY:	Aesculap® Implant Systems, 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
COMMON NAME:	S4 Cervical Occipital Plate Spinal System
CLASSIFICATION NAME:	Appliance, Fixation Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
REGULATION NUMBER:	888.3050/888.3070
PRODUCT CODE:	KWP/MNI/NKB

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant System (AIS), LLC. believes that the modifications made to the S4 Cervical Occipital Plating Spinal System is substantially equivalent to our predicate system (K062012).

DEVICE DESCRIPTION

The AIS® S4 Cervical Occipital Plate Spinal System is an implant system 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 occiptio-cervico-thoracic junction (occiput-T3). The AIS® S4 Cervical Occipital Plate Spinal System consists of plates, bone screws, rods, hooks, and connectors. The components are available in a variety of lengths in order to accommodate patient anatomy. The AIS® S4 Cervical Occipital Plate Spinal System is manufactured from Titanium/Titanium Alloy and will be provided non-sterile.

INDICATIONS FOR USE

When intended to promote fusion of the cervical spine and thoracic spine (C1-T3) and occipito-cervico-thoracic junction (occiput-T3) and are intended for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies

- Spondylolisthesis
- Spinal Stenosis
- Fracture/dislocation
- Failed previous fusion
- Atlanto/axial fracture with instability
- Occipitocervical dislocation
- Revision of previous cervical spine surgery
- Tumors

The occipital bone screws are limited to occipital fixation only. The hooks and rods are also intended to provide stabilization to promote fusion following reduction of fracture/dislocation or trauma in the cervical/upper thoracic (C1-T3) spine.

The use of the polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. Screws are not intended to be place in the cervical spine.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The AIS® S4 Cervical Occipital Plate Spinal System is considered substantially equivalent to other legally marketed predicate systems. The components of the system are offered in the same range of shapes and sizes as the existing Aesculap predicate device (K062012). Furthermore, the material used for the subject device is the same as that used to manufacture the predicate system.

PERFORMANCE DATA

Testing of the AIS® S4 Cervical Occipital Plating System was performed in accordance with ASTM F1717/F2067/F543 (static compression, static torsion, compression bending, torsion fatigue, and screw pull-out). Testing results demonstrate the Aesculap® Implant Systems SIBD Spinal System is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aesculap® Implant Systems, LLC
% Ms. Lisa M. Boyle
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

JUL 23 2010

Re: K100147
Trade/Device Name: Aesculap S4 Cervical Occipital Plate System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, KWP
Dated: July 01, 2010
Received: July 01, 2010

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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K100147

Device Name: Aesculap S4 Cervical Occipital Plate System

Indications for Use:

When intended to promote fusion of the cervical spine and thoracic spine (C1-T3) and occipito-cervico-thoracic junction (occiput-T3) and are intended for the following:

- DDD (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies
- Spondylolisthesis
- Spinal Stenosis
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The use of the polyaxial screws is limited to placement in T1-T3 in treating thoracic conditions only. Screws are not intended to be place in the cervical spine.

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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100147