K062012

B. 510(k) Summary & Certification

510(k) SUMMARY (as required by 21 CFR 807.92)
S4 Cervical Occipital Plate Spinal System
March 27, 2006

FEB 9 2007

COMPANY:	Aesculap®, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 2916714
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 Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease
REGULATION NUMBER:	888.3050/888.3070
PRODUCT CODE:	KWP/MNI/NKB

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the S4 Cervical Occipital Plate Spinal System is substantially equivalent to Depuy Acromed's Summit Occipito-Cervico-Thoracic (OCT) Spinal Systems and Aesculap's S4 Cervical Spinal System.

DEVICE DESCRIPTION

The Aesculap® 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 Aesculap 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 Aesculap® 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
- Rheumatoid Arthritis
- 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 Aesculap® S4 Cervical Occipital Plate Spinal System is considered substantially equivalent to other legally marketed predicate systems. Biomechanical testing of the subject device was found to be similar in performance to previously cleared spinal systems with similar indications.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the "Spinal System 510(k)s" was completed where relevant. Testing results demonstrate the Aesculap S4 Cervical Occipital Plate Spinal System is safe and effective comparable to other predicate systems currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap, Inc.
% Ms. Lisa M. Boyle
Regulatory Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

FEB 9 2007

Re: K062012
Trade/Device Name: S^4 Cervical Occipital Plate Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: III
Product Code: NKB, MNI, KWP
Dated: January 26, 2007
Received: January 29, 2007

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehler
for

Mark N. Melkerson
Director
Division of General, Restorative
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number:_____

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
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or trauma in the cervical/upper thoracic (C1-T3) spine.

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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)

Barbara Buehler

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K062012