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

APR 20 2009

S4 Spinal System
March 11, 2009

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)
lisa.boyle@aesculap.com (email)

TRADE NAME: S4

COMMON NAME: S4 Spinal System

DEVICE CLASS: Class III

PRODUCT CODE: NKB, MNI, MNH, and KWP

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

REVIEW PANEL: Orthopedics

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, Inc. believes that the S4 Spinal System additions are substantially equivalent to the existing components of the S4 Spinal System (K071945/K062085/K032219).

DEVICE DESCRIPTION

The S4 Spinal System consists of polyaxial screws and monoaxial screws of varying diameters and lengths, various hook styles, rods of varying lengths, and fixed and adjustable rod to 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, when used as a pedicle screw fixation system, is indicated for use in patients: a) having severe spondylolisthesis (Grade 3 and 4) at the L5-S1 join; b) who are receiving fusion using autogenous graft only; c) who are having the device fixed or

attached to the lumbar or sacral spine; and d) who are having the device removed after the development of a solid fusion mass may not go above the L5-S1 joint, the levels of pedicle screw fixation may span from L3 to the sacrum.

The S4 Spinal System is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spin: degenerative spondyloisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

When used as a hook and sacral screw system (other than pedicle screw fixation system for high grade spondylolisthesis), the S4 Spinal System is intended for use in the treatment of degenerative disc disease (as defined by chronic back pain of discogenic origin with the degeneration of the disc confirmed by a history and radiographic studies), idiopathic scoliosis, spondylolisthesis, kyphotic or lordotic deformity of the spine, loss of stability due to tumors, spinal stenosis, vertebral fracture of dislocation, pseudoarthrosis, and previous failed spinal surgery/fusion. When used for this indication, screws of the S4 Spinal System are intended for sacral/iliac attachment only. Hooks and transverse connectors of the system are intended for posterior throracic and/or lumbar use only. The levels of use for hook and sacral screw fixation of this system are T1 to the sacrum.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The new components of the 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

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 applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

APR 20 2009

Re: K090657
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 and KWP
Dated: April 14, 2009
Received: April 15, 2009

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

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

Enclosure

Page 1 of 1

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K090657

Device Name: S4 Spinal System

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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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices 002

510(k) Number K090657