

K090354

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

Aesculap Implant Systems Laminoplasty Plating System

January 15, 2009

COMPANY: Aesculap® Implant Systems (AIS), Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 6005673311

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

TRADE NAME: AIS Laminoplasty Plating System

COMMON NAME: Appliance, Fixation, Interlaminar

CLASSIFICATION NAME: Orthosis, Spine, Plate, Laminoplasty, Metal

REGULATION NUMBER: 21 CFR 888.3050

PRODUCT CODE: NQW

MAY 12 2009

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems (AIS) believes that the Laminoplasty Plating System is substantially equivalent to the Synthes Arch Fixation System (K032534).

DEVICE DESCRIPTION

The AIS Laminoplasty Plating System is an implant system comprised of various sizes of plates that are designed to fit anatomy of the elevated lamina. The plates have screw holes, which allow for attachment to the vertebral body and the allograft. The screws to be used with the plates are available in a 2mm length with various diameters and are designed to match the anatomical requirements. The AIS Laminoplasty Plating System is manufactured from Titanium/Titanium Alloy and will be provided non-sterile and or sterile.

INDICATIONS FOR USE

The AIS Laminoplasty Plating System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The AIS Laminoplasty Plating System holds or buttresses the allograft in place in order to prevent expulsion of the allograft, or impingement of the spinal cord.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The AIS Laminoplasty Plating 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All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable.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 AIS Laminoplasty Plating System is safe and effective comparable to other predicate systems currently on the market.



Aesculap® Implant Systems (AIS), Inc.
% Ms. Lisa M. Boyle
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

MAY 12 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K090354

Trade/Device Name: Aesculap Implant System Laminoplasty Plating System

Regulation Number: 21 CFR 888.3050

Regulation Name: Spinal interlaminar fixation orthosis

Regulatory Class: II

Product Code: NQW

Dated: February 9, 2009

Received: February 11, 2009

Dear Ms. Stanners:

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 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

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: _____

Device Name: **Aesculap Implant Systems Laminoplasty Plating System**

Indications for Use:

The Aesculap Implant Systems Laminoplasty Plating System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Laminoplasty Plating System holds or buttresses the allograft in place in order to prevent expulsion of the allograft, or impingement of the spinal cord.

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)

[Handwritten Signature] for M/M

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

510(k) Number K090354