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

Aesculap® Implant Systems SIBD Spinal System
July 20, 2010

JUL 20 2010

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)

TRADE NAME: Aesculap® Implant Systems SIBD Spinal System

COMMON NAME: Spinal Implants

CLASSIFICATION NAME: Intervertebral Fusion Device with Bone Graft, Lumbar

REGULATION NUMBER: 888.3080

PRODUCT CODE: MAX

PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the Aesculap® Implant Systems SIBD Spinal System.

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems, Inc. believes that the SIBD Spinal System is substantially equivalent to the Aesculap® Implant Systems PEEK Spinal Implant System (K071983), Synthes SynFix-LR Spacer (K072253), Biomet Spine Solitaire Anterior Spinal System (K081395), the LDR Spine ROI Interbody Fusion System (K082262), the Life Spine Stand Alone Spacer System (K091301), and the Surgicraft STALIF TT System (K073109).

DEVICE DESCRIPTION

The Aesculap® Implant Systems SIBD Spinal System is an implantable spinal device manufactured from polyetheretherketone (PEEK) with tantalum markers. The implant is secured to vertebral bodies by four titanium screws inserted through the anterior screw holes. The implants are offered in a variety of shapes and sizes to meet the requirements of the individual patient anatomy.

INDICATIONS FOR USE

The SIBD Spinal System is a stand-alone device intended to be used with the four supplied bone screws if no supplement fixation is used.

As an intervertebral body fusion device designed for use with auto graft, the SIBD Spinal System is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s).

Patients should be skeletally mature and must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Aesculap® Implant Systems device.

TECHNOLIGICAL CHARACTERISTICS (compared to Predicate(s))

The components of the Aesculap® Implant Systems SIBD Spinal System are offered in the same range of shapes and sizes as the predicate devices. The material used for the Aesculap® Implant Systems device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

Static and dynamic testing of the Aesculap® Implant Systems SIBD Spinal System was performed in accordance with ASTM F2077/F2267 (static and dynamic axial compression, static & dynamic shear compression, static & dynamic torsion, subsidence, and expulsion testing) as recommended by the FDA Class II Special Controls Guidance Document: Intervertebral Body Fusion Device. 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-G
Silver Spring, MD 20993-0002

Aesculap® Implant Systems, Inc.
% Ms. Lisa M. Boyle
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

SEP 12 2011

Re: K100802
Trade/Device Name: Aesculap® Implant Systems SIBD Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: June 10, 2010
Received: June 14, 2010

Dear Ms. Boyle:

This letter corrects our substantially equivalent letter of July 20, 2010.

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 (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 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: K100802

Device Name: Aesculap® Implant Systems SIBD Spinal System

Indications for Use:

The SIBD Spinal System is a stand-alone device intended to be used with the four supplied bone screws if no supplement fixation is used.

As an intervertebral body fusion device designed for use with autograft, the SIBD Spinal System is intended for spinal fusion procedures at one or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients may have had previous non-fusion spinal surgery at the involved spinal level(s).

Patients should be skeletally mature and must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the Aesculap® Implant Systems device.

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

(per 21 CFR 801.109)

(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 K100802