K083311

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

Aesculap CeSpace PEEK Spinal Implant System

7 November 2008

MAR - 4 2009

COMPANY:	Aesculap®Implant Systems, Inc. 3773 Corporate Parkway Center Valley, PA 18034 Establishment Registration Number: 3005673311
CONTACT:	Matthew M. Hull 800-258-1946 (phone) 610-791-6882 (fax)

TRADE NAME:	Aesculap CeSpace PEEK Spinal Implant System
COMMON NAME:	Intervertebral Fusion Device w/ Bone Graft, Cervical
CLASSIFICATION NAME:	Orthosis, Spinal Intervertebral Fusion
REGULATION NUMBER:	888.3080
PRODUCT CODE:	ODP, MQP

SUBSTANTIAL EQUIVALENCE

Aesculap® Implant Systems, Inc. believes that the Aesculap Cespace PEEK Spinal Implant System is substantially equivalent to the Aesculap PEEK VBR and Intervertebral Body Fusion Systems (K060762 & K071983), the Spinal Elements Crystal cervical interbody fusion devices (K073351).

DEVICE DESCRIPTION

The Aesculap CeSpace PEEK Spinal Implant System is a cervical intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. Components are offered in a variety of sizes to meet the requirements of the individual patient anatomy. Components are manufactured from PEEK – Optima (per ASTM F2026).

INDICATIONS FOR USE

When used as a Vertebral Body Replacement Device:

The Aesculap PEEK Spinal Implant System is indicated for use in the thoracolumbar spine (T1 to L5) for partial or total replacement of a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e. fracture) to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System implants can be used individually or in pairs. The Aesculap PEEK Spinal Implant System is also intended for use with bone graft.

When used as an Intervertebral Body Fusion System:

The Aesculap PEEK Spinal Implant System consists of CeSpace PEEK Implants that are circular in shape with flattened sides. The CeSpace implants are indicated for spinal fusion procedures at one level (C3-C7) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Aesculap PEEK Spinal Implant System is intended for use with supplemental spinal fixation systems such as the Aesculap S4 System. The Aesculap PEEK Spinal Implant System is also intended for use with autogenous bone graft.

Patients must have undergone a regimen of at least six (6) weeks of non-operative treatment prior to being treated with the Aesculap device.

TECHNOLIGICAL CHARACTERISTICS(compared to Predicate(s))

The implants in the Aesculap CeSpace PEEK Spinal Implant System are offered in the same range of shapes and sizes as the predicate devices. The material used for the Aesculap device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

Static and dynamic testing of the Aesculap PEEK Spinal Implant System was performed in accordance with ASTM F2077 and/or F1717 as recommended by the FDA Class II Special Controls Guidance Document: Intervertebral Body Fusion Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap® Implant System, Inc.
% Mr. Matthew M. Hull
3733 Corporate Parkway
Center Valley, Pennsylvania 18034

MAR 4 2009

Re: K083311
Trade/Device Name: Aesculap CeSpace PEEK Intervetebral Body Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP
Dated: February 10, 2009
Received: February 11, 2009

Dear Mr. Hull:

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 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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

K083311

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K083311

Device Name: Aesculap CeSpace PEEK Intervertebral Body Fusion System

Indications for Use:

When used as a Vertebral Body Replacement Device:

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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 General, Res
and Neurological Device

510(k) Number K083311