

K980484

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
in Accordance with SMDA of 1990

AESCULAP SPINE SYSTEM® EVOLUTION

September 25, 1998

Company

Aesculap®, Inc.
1000 Gateway Blvd.
So. San Francisco, CA 94080

Contact

Lia S. Jones, Regulatory Associate
Phone: 650-876-7000 x 350
FAX: 650-589-3007

Trade Name

Aesculap Spine System® Evolution

Common Name

Spinal Fixation System

Product Code and Regulatory Classification

MNI:	888.3070	Pedicle Screw Spinal Fixation Orthosis
MNH:	unclassified	Spondylolisthesis Spinal Fixation Device System
KWP:	888.3050	Spinal Interlaminar Fixation Orthosis

Product Classification

Class II

Intended Use

When used as a pedicle screw fixation system, Aesculap's Spine System® Evolution is 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 spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

It is also intended for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. Levels of pedicle screw fixation for this indication are from L₃-S₁.

When used as a non-pedicle screw system, Aesculap's Spine System® Evolution is indicated for use in patients with degenerative disc disease (defined as back pain of discongenetic origin with degeneration of the disc confirmed by history and radiographic studies), kyphosis, spondylolisthesis, neurological scoliosis, spine tumors and fractures. It is intended for posterior fixation from levels T1 through S1.

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
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AESCULAP SPINE SYSTEM® EVOLUTION

Device Description

Spine System® Evolution is a multiple component system comprised of a variety of single use devices that allow the surgeon to build a spinal implant construct in order to stabilize the thoracic and lumbar vertebrae and promote spinal fusion. Spine System® Evolution consists of pedicle screws (monoaxial and polyaxial), rods, linking plates, lateral connectors, and other implant components used to lock the desired construct in place. The spinal implants are manufactured from titanium alloy (Ti6Al4V) in accordance to ISO 5832/III. The specialized instrumentation used to implant and explant the Spine System® Evolution implants are made from surgical grade stainless steel in accordance to ISO 7153/I.

Performance Data

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the components that comprise Spine System® Evolution were subjected to mechanical testing according to the ASTM Standard F 1717-96 (Static and Fatigue Test Methods for Spinal Implant Constructs in a Corpectomy Model).

Substantial Equivalence

Aesculap believes that the Spine System® Evolution additional components presented in this submission are substantially equivalent in design, material composition, function and intended use to currently marketed spinal implant systems, such as:

- **Spine System®**
by Aesculap (K962757, K953599, K935113)
- **CD Horizon™ Spinal System**
by Sofamor Danek (K964159, K962708, K961633)
- **Mirage™ Spinal System**
by Alphatec (K951846)
- **Moss® Miami Titanium Spinal System**
by Depuy Motech™ (K980447, K955348)
- **Synergy™ Posterior Spinal System**
by Cross® Medical Products, Inc. (K973836, K950099, K940631)



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lia S. Jones
Regulatory Associate
Aesculap®, Inc.
1000 Gateway Boulevard
South San Francisco, California 94080-7030

Re: K980484
Spine System® Evolution
Regulatory Class: II
Product Codes: MNI, KWP, and MNH
Dated: August 20, 1998
Received: August 21, 1998

Dear Ms. Jones:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

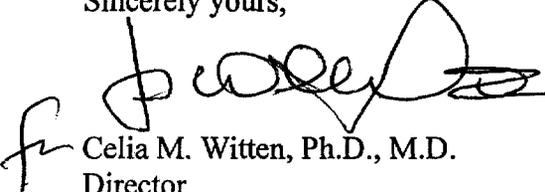
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", is written over the typed name. The signature is fluid and cursive.

Celia M. Witten, Ph.D., M.D.
Director
Division of General
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number (if known): K980484

Device Name: **Aesculap Spine System® Evolution**

Indication for Use:

When used as a pedicle screw fixation system, Aesculap's Spine System® Evolution is 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 spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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(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 Devices
510(k) Number K980484

Prescription Use X
(per 21 CFR 801.109)

or

Over-the-Counter Use _____

(Optional Format 1-2-96)

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