

JUN 10 1998

Amendment #1 to #K980121

Aesculap Spine System® Additional Components

510(k) Summary of Safety and Effectiveness in Accordance with SMDA of 1990
Aesculap Spine System® Additional Components

Submitted:
January 9, 1997

K 980121

Company

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

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Product

Aesculap Spine System® Additional Components

Common Names

Lateral Connectors
Smooth Rods

Classification Names and Product Codes

KWP - Spinal Interlaminar Fixation Orthosis
MNH - Spondylolisthesis Spinal Fixation Device System

Product Classification

Class II

Regulatory Classification

21 CFR Section 888.3050
Spinal Interlaminar Fixation Orthosis
unclassified
Spondylolisthesis Spinal Fixation Device System

Intended Use

When used as a non-pedicle screw fixation system, the Aesculap Spine System® is indicated for use in patients with degenerative disc disease (defined as back pain of discongenic 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.

When used as a pedicle system, the Spine System® is intended only for patients (a) having severe spondylolisthesis (Grade 3 or 4 at the L₅-S₁ vertebral joint; (b) who are receiving fusions using autologous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (note: levels of pedicle screw fixation for this indication are from L₃-S₁); and (d) who are having the device removed after the development of a solid fusion mass.

III. Device Information

B. Intended Use

When used as a non-pedicle screw fixation system, the Aesculap Spine System® is indicated for use in patients with degenerative disc disease (defined as back pain of discogenic 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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A picture of the Spine System® construct attached to a spinal model is on the following page. Please note the construct contains a lateral connector and a **knurled** rod. Pictures of the new smooth rods can be found in the biomechanical report (see Appendix C).



JUN 10 1998

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: K980121
Lateral Connectors and Smooth Rods for Aesculap Spine System®
Regulatory Class: II
Product Codes: MNH and KWP
Dated: May 4, 1998
Received: May 5, 1998

Dear Ms. Jones:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal, Food, Drug, and Cosmetic Act (Act). This decision is based on your device system being found equivalent only to similar device systems labeled and intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. You may, therefore, market your device system subject to the general controls provisions of the Act and the limitations identified below.

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. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment for indications other than severe spondylolisthesis, as described above, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than severe spondylolisthesis, as described above, is a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system using pedicle screws is intended only for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral

joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

2. You may not label or in anyway promote this device system for pedicular, screw fixation/attachment to the cervical, thoracic or lumbar vertebral column for intended uses other than severe spondylolisthesis, as described above. The package insert must include the following statements:

WARNINGS:

- When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral (L5-S1) vertebral joint.
- The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.
- Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
- Potential risks identified with the use of this device system, which may require additional surgery, include:

device component fracture,
loss of fixation,
non-union,
fracture of the vertebra,
neurological injury, and
vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

3. Any pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described by item 1, for this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.
4. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

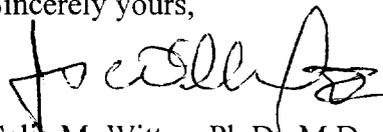
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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.

FDA advises that the use of your device system with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or those of other manufacturers, may also be required.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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" (21 CFR 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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


f 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): #K980121

Device Name: Aesculap Spine System® Additional Components:
Lateral Connectors and Smooth Rods

Indication for Use:

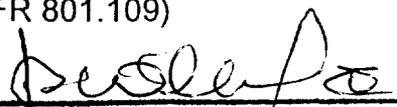
When used as a non-pedicle screw fixation system, the Aesculap Spine System® is indicated for use in patients with degenerative disc disease (defined as back pain of discongenic origin with degeneration of the disc confirmed by history and radiographic studies), kyphosis, spondylolisthesis, neurological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

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-the-Counter Use
(per 21 CFR 801.109)



(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980121