JAN 13 2000

K993551

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

SOCON® SPINAL SYSTEM
EXPANDED PEDICLE SCREW INDICATIONS

October 19, 1999

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

CONTACT: Lia S. Jones, Regulatory Associate
650-624-5073 (phone)
650-589-3007 (fax)
lia.jones@aesculap.com (email)

TRADE NAME: SOCON® Spinal System

COMMON NAME: Pedicle Screw Spinal Fixation System

DEVICE CLASS: Class II

PRODUCT CODE: MNH, MNI

CLASSIFICATION: 888.3070 – Spondylolisthesis Spinal Fixation Device System
888.3070 – Pedicle Screw Spinal System

REVIEW PANEL: Orthopedic Devices Branch
Division of General and Restorative Devices

DEVICE DESCRIPTION

The SOCON® Spinal System is a multiple component system comprised of a variety of single-use, non-sterile devices that allow the surgeon to build a spinal implant construct in order to provide stabilization and promote spinal fusion. The implants are manufactured from titanium alloy, Ti6A14V, in accordance to ISO 5832/3 and include pedicle bone screws, straight and pre-bent rods, cross bars and self-locking clamps. Specialized instrumentation made from surgical grade stainless steel in accordance to ISO 7153/1 is available for the application and removal of the SOCON implants.

PURPOSE FOR PREMARKET NOTIFICATION

The sole purpose of this 510(k) is to expand the Indications for Use for Aesculap's current SOCON® Spinal System (#K970285) based on the FDA's publication of the final rule for pedicle screw systems (Federal Register, Vol. 63, No. 143) which became effective on August 26, 1998.

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October 19, 1999

INTENDED USE

The SOCON® Spinal System is a pedicle screw system indicated 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 (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

In addition, the SOCON® Spinal System 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).

SUBSTANTIAL EQUIVALENCE

There have been no design modifications or technological changes to the current SOCON® Spinal System since receiving FDA clearance under #K970285, and therefore it is substantially equivalent to itself.

For the purpose of this 510(k), however, the expanded Indications for Use are based on the FDA's publication of the final rule for pedicle screw systems (Federal Register, Vol. 63, No. 143) and is substantially equivalent to the recently cleared **VSP System (Pedicle Screw Indications) by DePuy AcroMed, Inc. under #K984350.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2000

Ms. Lia S. Jones
Regulatory Associate
Aesculap , Inc.
1000 Gateway Boulevard
South San Francisco, California 94080-7028

Re: K993551
Trade Name: SOCON® Spinal System
Regulatory Class: II
Product Code: MNH and MNI
Dated: October 19, 1999
Received: October 20, 1999

Dear Ms. Jones:

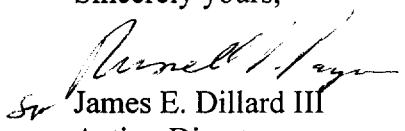
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 control provisions of the Act. The general control 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 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.

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" (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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K993551

Device Name: **SOCON® Spinal System**
Expanded Pedicle Screw Indications

Indication for Use:

The SOCON® Spinal System is a pedicle screw system indicated 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 (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

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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 K993551

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)