APR 1 1 2005

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

in Accordance with SMDA of 1990

SPECTRUM™ Cervical Spinal System

March 29, 2005

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Kathy A. Racosky, Regulatory Affairs Associate
800-258-1946 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com (e-mail)

TRADE NAME: SPECTRUM™ Cervical Spinal System

COMMON NAME: Plate and Screw Cervical Spinal Fixation System

DEVICE CLASS: Class II

PRODUCT CODE: KWQ

CLASSIFICATION: 888.3060 – Appliance, Fixation, Spinal Intervertebral Body

REVIEW PANEL: Orthopedic

INTENDED USE

The SPECTRUM™ Cervical Plating System is intended for anterior intervertebral body screw fixation of the cervical spine. The system implants are indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disk confirmed by patient history and radiographic studies), trauma (including fractures or dislocation), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/of failed previous fusions.

WARNING: This device is not approved for screw attachment of fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

DEVICE DESCRIPTION

The SPECTRUM™ Cervical Spinal System consists of a variety of shapes and sizes of bone plates (locking mechanism is pre-assembled to plates), screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The implants for this system are manufactured from Titanium alloy (Ti6Al4V) in conformance with ISO 5832/3 (ASTM F136-98) and are provided non-sterile.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The modified components conform to ASTM standard F1717, applicable ISO standards, and the CDRH Guidance for Spinal System 510(k).

SUBSTANTIAL EQUIVALENCE

Aesculap believes that the modified SPECTRUM™ Cervical Spinal System is substantially equivalent to our current SPECTRUM™ Cervical Spinal System (K022997) and to the following competitor's predicate device.

- Sofamor Danek Atlantis™ Anterior Cervical Plate System (K993855)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2005

Ms. Kathy A. Racosky
Regulatory Affairs Associate
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K050804
Trade/Device Name: SPECTRUM™ Cervical Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: March 29, 2005
Received: March 30, 2005

Dear Ms. Racosky:

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 Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K050804

Device Name: SPECTRUM™ Cervical Spine System

Indication for Use:

The SPECTRUM™ Cervical Plating System is intended for anterior intervertebral body screw fixation of the cervical spine. The system implants are indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disk confirmed by patient history and radiographic studies), trauma (including fractures or dislocation), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/of failed previous fusions.

WARNING: This device is not approved for screw attachment of fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109) (Optional Format 3-10-98)

(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, and Neurological Devices

510(k) Number K050804