JUL 25 2003

K032059

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

MACS^{TL} Modular Anterior Construct System

July 1, 2003

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

CONTACT: Georg Keller, Regulatory Affairs Manager
800-258-1946 (phone)
610-791-6882 (fax)
georg.keller@aesculap.com (e-mail)

TRADE NAME: MACS^{TL} Modular Anterior Construct System

COMMON NAME: Anterior Lateral Spinal Stabilization System

DEVICE CLASS: Class II

PRODUCT CODE: KWQ

CLASSIFICATION: 888.3060 - Appliance, Fixation, Spinal Intervertebral Body

REVIEW PANEL: Orthopedic

INTENDED USE

This anterolateral / anterior system consists of several vertebral screws, locking nuts, spine plates and rods. The points of attachment are screw fixation to the anterolateral vertebral bodies of the lumbar and thoracic spine (T1-L5). This system is intended to provide stabilization during the development of a solid spinal fusion. When used as an anterolateral / anterior spine plate and rod system, the MACS^{TL} Modular Anterior Construct System is indicated for patients with:

- Degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Spondylolysis
- Fracture
- Spinal stenosis
- Deformities (i.e., scoliosis, kyphosis, lordosis, whether neuromuscular or related to deficient posterior elements)
- Tumors (neoplastic disease)
- Pseudarthrosis
- Revision of previous surgery

DEVICE DESCRIPTION

The MACS^{TL} Polyaxial Screw and Thoracic Line is an extension of the existing MACS^{TL} implant system, cleared through 510(k) K002824 on May 8, 2001. The extension consists of a larger Polyaxial screw, as well as, a shorter Polyaxial screw for the Thoracic spine. The MACS^{TL} Polyaxial screw with the larger diameter (10mm) is also designed to work as a rescue screw in poor bone quality.

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The new MACS^{TL} System conforms to applicable ASTM and ISO standards.

SUBSTANTIAL EQUIVALENCE

Aesculap believes that the MACS^{TL} Modular Anterior Construct System Line Extension is substantially equivalent to the existing MACS^{TL} Modular Anterior Construct System (K002824) and the following other predicate devices:

- MACS^{TL} HMA Anterior Spinal Stabilization System (K011556)
- K-Centrum Anterior Spinal Fixation System (K990959 & K002371)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2003

Mr. Georg Keller
Regulatory Affairs Manager
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K032059
Trade/Device Name: MACS^{TL} Modular Anterior Construct System
Regulatory Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: June 1, 2003
Received: June 2, 2003

Dear Mr. Keller:

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.

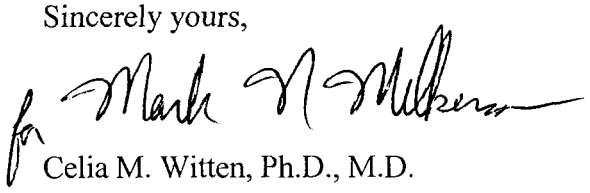
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4639. 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/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
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): K032059

Device Name: MACS^{TL} Modular Anterior Construct System

Indication for Use:

This anterolateral / anterior system consists of several vertebral screws, locking nuts, spine plates and rods. The points of attachment are screw fixation to the anterolateral vertebral bodies of the lumbar and thoracic spine (T1-L5). This system is intended to provide stabilization during the development of a solid spinal fusion. When used as an anterolateral / anterior spine plate and rod system, the MACS^{TL} Modular Anterior Construct System is indicated for patients with:

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- Pseudarthrosis
- Revision of previous surgery

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-the-Counter Use _____

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

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032059