K033148

510(k) Summary

Date
September 29, 2003

APR 1 2 2004

Submitter
Advanced Medical Technologies AG
Kasteler Strasse 11
66620 Nonnweiler-Braunshausen
Germany

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Anterior vertebral body fixation system

Classification name
Spinal Intervertebral Body Fixation Orthosis (per 21 CFR section 888.3060)

Equivalent Device
The ART Anterior Spinal System is similar in material and indications as the Kaneda SR Anterior Spinal System (DePuy Acromed, K971248) and the M-2 Anterior Plate (DePuy Acromed, K972718).

Device Description
The ART Anterior Spinal System consists of a Plate that attaches to the anterior or antero-lateral vertebral body of the thoraco-lumbar and lumbar spine. One plate is place on each vertebral body. The single size plate is attached to the vertebral body with two diverging Ø6.5mm Screws. The superior portion of the plate is U-shaped to receive a Ø6mm Rod. The inner surface of the U-shaped opening of the plate is threaded to receive a Locking Nut. When tightened the Locking Nut firmly secures the Rod to the Plate. In this manner the Rods connect two or more Plates. See schematic in Exhibit III.

A rod connector component, called a Domino, attaches two rods for use in multi-level fusions. Rods can be connected in series or parallel.

Intended Use
The ART Anterior Spinal System is intended for anterolateral screw fixation of the T6-L5 spine.

Indications for use include:

- degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal stenosis
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- tumor
- pseudoarthrosis
- failed previous fusion

Summary Nonclinical Tests
Testing was performed according to ASTM F1717.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2004

Mr. J.D. Webb
Advanced Medical Technologies
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K033148
Trade Name: ART Anterior Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 19, 2004
Received: January 21, 2004

Dear Mr. Webb:

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) 594-4659. 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

510(k) number (if known): K033148

Device Name: ART Anterior Spinal System

Indications for Use:

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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 ✓
(per 21 CFR 801.109)

OR

Over-the-Counter Use ____

(Optional format 1-2-96) ____

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

510(k) Number K033148

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

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