JUN 17 2004

K040721
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III. 510(K) Summary

SUBMITTED BY:

Globus Medical Inc.
303 Schell Lane
Phoenixville, PA 19460
(610) 415-9000 x218
Contact: Kelly J. Baker
Prepared: March 18, 2004

DEVICE NAME:

ASSURE™ Anterior Cervical Plate System

CLASSIFICATION:

The device classification is Class II as per 21 CFR §888.3060 Spinal Intervertebral Body Fixation Orthosis. The product code is KWQ.
The panel code is 87.

PREDICATE DEVICES:

Synthes CSLP: K926453, SE date October 12, 1993; K030866, April 18, 2003.
Depuy PEAK: K971730, SE date November 3, 1997.
Howmedica Osteonics (Stryker) Reflex: K031702, SE date August 8, 2003.
The product code for these devices is KWQ.

DEVICE DESCRIPTION:

The ASSURE™ Anterior Cervical Plate System consists of plates used with either standard screws or rigid screws and set screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (levels C2-C7). The implants are composed of titanium alloy.

INTENDED USE:

The ASSURE™ Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine C2-C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

PERFORMANCE DATA:

Static and dynamic mechanical testing, in accordance with ASTM F1717, was conducted to evaluate performance, as a basis for substantial equivalence.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The ASSURE™ Anterior Cervical Plate System implants are similar to the predicate Synthes CSLP (K926453, K030866), Depuy PEAK (K971730), Howmedica Osteonics (Stryker) Reflex (K031702), anterior cervical plate systems with respect to technical characteristics and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Globus Medical Inc.
c/o Kelly J. Baker, Ph.D.
303 Schell Lane
Phoenixville, PA 19460

Re: K040721
Trade/Device Name: ASSURE™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 18, 2004
Received: March 19, 2004

Dear Dr. Baker:

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.

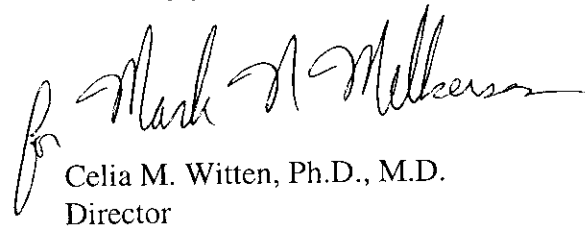
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

II. Indications for Use Statement

510(k) Number: K040721

Device Name: ASSURE™ Anterior Cervical Plate System

Indications:

The ASSURE™ Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine C2-C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, failed previous fusion, spondylolisthesis, and spinal stenosis.

Prescription Use ___X___ OR Over-The-Counter Use___
(Per 21 CFR §801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

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