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K032534
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3.0 Summary of Safety and Effectiveness Information

SPONSOR:

Synthes USA
1230 Wilson Drive
West Chester, PA 19380
(484) 356-9614
Contact: Susan Lewandowski

DEVICE NAME:

Synthes Arch™ Fixation System (AFS)

CLASSIFICATION:

21 CFR §888.3050: Spinal interlaminal fixation orthosis.
Product code: NQW

COMMON NAME:

Appliance, fixation, interlaminal

PREDICATE DEVICE:

Plate, fixation, bone:
K963741 – Howmedica Leibinger Inc.
K961485 – Howmedica Inc.
K961497 – Howmedica Inc.
Bone fixation Cerclage:
K850631 – Kirschner Medical Corp.

DEVICE DESCRIPTION:

The Synthes AFS is comprised of various sized, pre-bent mini-plates that are designed to fit the anatomy of the vertebral arch (i.e., between the pedicle and spinous process). The plates have screw holes located at the center and both ends of the plate to allow for attachment to the bone. The center hole in the plate is used for attachment to bone allograft. The plates are composed of commercially pure titanium which conforms to ASTM F67.

The screws intended for use with the mini-plates are available in a variety of lengths and diameter and are designed to match the anatomical requirements. The screws are composed of titanium alloy, Ti6Al7Nb, which conforms to ASTM F1295.

The Synthes AFS is designed to be used in conjunction with the components that comprise previously cleared Synthes posterior cervical spine products.

INTENDED USE:

The Synthes AFS is indicated for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Arch Fixation System holds or buttresses the

allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.

MATERIAL: All components of the Synthes AFS are manufactured from commercially pure titanium (ASTM F67) or titanium alloy Ti6Al7Nb (ASTM F1295).

PERFORMANCE DATA: Performance characteristics comparing the Synthes AFS to performance characteristics of commercially available devices were provided to support a determination of substantial equivalence.

BASIS OF SUBSTANTIAL EQUIVALENCE: The Synthes AFS implants are similar in design, material and performance to currently marketed orthopedic implants. The intended use of the product as a buttress plate is substantially equivalent to information presented on the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2004

Ms. Susan Lewandowski
Project Manager, Regulatory Affairs
Synthes (USA)
1230 Wilson Drive
West Chester, Pennsylvania 19380

Re: K032534
Trade/Device Name: Synthes Arch™ Fixation System (AFS)
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: NQW
Dated: January 2, 2004
Received: January 5, 2004

Dear Ms. Lewandowski:

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" (21 CFR 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,

for Mark N. Melkerson

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

2.0 Indications for Use Statement

510(k) Number (if known): K032534

Device Name: Synthes Arch™ Fixation System (AFS)

Indications:

The Synthes Arch™ Fixation System is intended for use in the lower cervical and upper thoracic spine (C3-T3) after a laminoplasty has been performed. The Arch™ Fixation System holds or buttresses the allograft in place in order to prevent the allograft from expulsion or impinging on the spinal cord.

(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)

for Mark N Milhous

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

510(k) Number K032534