

DEC 16 1998

K983967

510(K) SUMMARY



Date: October 29, 1998 **CORPORATE HEADQUARTERS**

Company: Biomet, Inc.
P.O. Box 587
Airport Industrial Park
Warsaw, Indiana 46581-0587

Device Name: Pediatric Osteotomy Plates
Common Name: Osteotomy Plates
Classification: Plate, fixation, bone (21 CFR 888.3030) class II

Device Description: Pediatric Osteotomy Plates are made from surgical implant grade 316LVM Stainless Steel conforming to the American Society for Testing and Materials (ASTM) material standard ASTM F-138. The plates are affixed to bone utilizing currently marketed stainless steel bone screws. The plates are available in sizes suitable for use in infants, children, and adolescents. Special instrumentation is available including plate driver/extractors, chisels, goniometer guides, impactors, slide hammers, clamps, and guide wires.

Intended Use: Pediatric Osteotomy Plates are indicated for fixation of intertrochanteric osteotomies for treating congenital or traumatic deformities in children.

Substantially Equivalent Devices:

Smith and Nephew Orthopaedics, Memphis, Tennessee
Infant, Child, and Adolescent Osteotomy Blade Plates

Zimmer, Inc., Warsaw, Indiana
Intertrochanteric Osteotomy Blade-Plates for Children

Synthes, Inc., Paoli, Pennsylvania
Right Angled Plates for Intertrochanteric Femur Osteotomies in Infants, Children, and Adolescents

The substantially equivalent devices are all similar in design and materials. The Biomet manufactured Pediatric Osteotomy plates do not raise any different questions regarding safety and effectiveness from the predicate devices.

Potential Adverse Effects for Metallic Internal Fixation Devices:

- Nonunion or delayed healing of bone
- Implant breakage, bending, or migration
- Fracture of bone
- Infection
- Allergic reaction to foreign body

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 16 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Lonnie Witham
Senior Regulatory Affairs Specialist
Biomet Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K983967
Trade Name: Pediatric Osteotomy Plates
Regulatory Class: II
Product Code: HRS
Dated: October 28, 1998
Received: November 6, 1998

Dear Mr. Witham:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

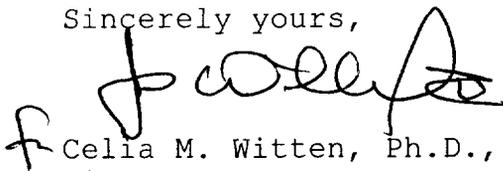
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Lonnie Witham

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number: K983967

Device Name: Pediatric Osteotomy Plates

Indications For Use: Pediatric Osteotomy Plates are indicated for fixation of intertrochanteric osteotomies for treating congenital or traumatic deformities in children.

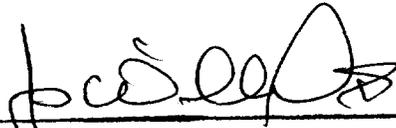
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use
(Optional Format 1-2-96)



(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

 K983967

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