

AUG 26 2002

K022531



SUMMARY OF SAFETY AND EFFECTIVENESS

- Sponsor:** Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587
- Contact Person:** Tracy J. Bickel
(574) 267-6639
- Proprietary Name:** 2mm Flexible Pediatric Nail
- Common Name:** Intramedullary Rod
- Classification Name:** Smooth or threaded metallic bone fastener (21 CFR 888.3040)
- Substantially Equivalent Devices:** Pediatric Fixation Rods- K000764
- Device Description:** The device is the same as flexible pins and ender nails that have been used to fix fractures in long bones for years in an intramedullary fashion. When these types of nails are used they will be used opposingly in pairs. The nail will be bent to provide three-point fixation. The ideal fixation points will be at the insertion site, the fracture site, and some point beyond the fracture site.
- Indications for Use:** Flexible Pediatric Fixation Nails are to be used for treatment of long-bone fractures including non-comminuted and comminuted mid-shaft fractures, subtrochanteric fractures, distal third fractures, combination fractures of the shaft and neck, intertrochanteric fractures, combination intertrochanteric and subtrochanteric fractures.
- Summary of Technologies:** The device's technological characteristics (materials, design, sizing, and indications) are similar or identical to the predicate device.
- Non-Clinical Testing:** An engineering justification was used to determine that the 2mm flexible pediatric nail presented no new risks and were; therefore, substantially equivalent to the predicate device.
- Clinical Testing:** None provided as a basis for substantial equivalence.

All trademarks are property of Biomet, Inc.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2002

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K022531

Trade/Device Name: 2mm Flexible Pediatric Nail
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: July 30, 2002
Received: July 31, 2002

Dear Ms. Bickel:

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.

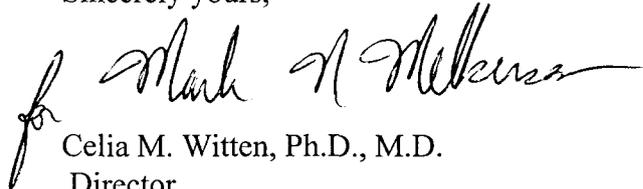
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Ms. Tracy J. Bickel

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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

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, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

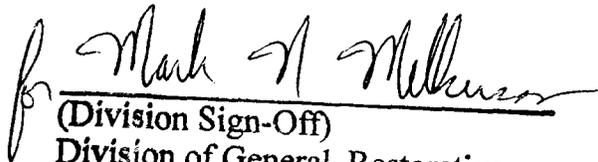
Enclosure

510(k) Number (if known): K022531

Device Name: **2mm Flexible Pediatric Nail**

Indications for Use:

Flexible Pediatric Fixation Nails are to be used for treatment of long-bone fractures including non-comminuted and comminuted mid-shaft fractures, subtrochanteric fractures, distal third fractures, combination fractures of the shaft and neck, intertrochanteric fractures, combination intertrochanteric and subtrochanteric fractures.



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

510(k) Number K022531

(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)