K042409 .12

DEC - 2 2004

BIOMET

510(k) Summary

Applicant/Sponsor: Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Contact Person: Gary Baker
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587
Phone: (574) 267-6639 ext. 1568
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Proprietary Name: Modular Arthrodesis Nail

Common Name: Titanium Intramedullary Rod

Classification Name: Rod, Fixation, Intramedullary and Accessories (21 CFR §888.3020)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Wichita® Fusion Nail – Howmedica Inc. (K993603)
Titanium Intramedullary Nails – Biomet Inc. (K982953)
T2 Arthrodesis Nail System – Howmedica Inc. (K020384)
Orthopedic Salvage System – Biomet Inc. (K002757)

Device Description:
The Modular Arthrodesis Nail is a multi-component device designed to provide arthrodesis fixation of the knee. The device has a central locking collar that connects femoral and tibial adapter segments. The adapter segments are available in two resection lengths (1 cm or 3 cm), each with two body styles (standard or elliptical). All components of the Modular Arthrodesis Nail are manufactured from Ti-6Al-4V titanium alloy conforming to ASTM F-136.

Intended Use:
The primary indication for these devices is the replacement of segmental defects of long bone, including midshaft replacement, and arthrodesis of the knee.

Indications include:

1. Treatment of patients who are not candidates for total knee arthroplasty.
2. Irretrievably failed total knee arthroplasty
3. Limb salvage in oncology surgery,

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4. Trauma
5. Any other condition where there is little soft tissue or bony tissue available for support, and arthrodesis is the treatment of choice.

These devices are intended for cemented use only.

Summary of Technologies: The Modular Arthrodesis Nail has the same intended use (arthrodesis), the same functional characteristics (rigid fixation) as the predicate devices, and is made of the same titanium alloy material as the predicate Titanium Intramedullary Nails and Orthopedic Salvage System (OSS) components used with the Modular Arthrodesis Nail.

Non-Clinical Testing: Mechanical testing indicated that the Modular Arthrodesis Nails are substantially equivalent to the predicate devices for the uses indicated.

Clinical Testing: Clinical testing was not required for these components to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 2 2004

Mr. Gary Baker
Regulatory Specialist
Biomet Manufacturing Corp.
56 East Bell DR. P.O. Box 587
Warsaw, IN 46581

Re: K042409
Trade/Device Name: Modular Arthrodesis Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: September 2, 2004
Received: September 3, 2004

Dear Mr. 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 (240) 276-0120. 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

Statement of Indications For Use

510(k) Number (IF KNOWN): K042409

Device Name: Modular Arthrodesis Nail

Indications for Use:

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4. Trauma
5. Any other condition where there is little soft tissue or bony tissue available for support, and arthrodesis is the treatment of choice.

These devices are intended for cemented use only.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-the-Counter Use_____ (Per 21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K042409