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BIOMET TRAUMA

AUG 17 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter:	Biomet Trauma 100 Interpace Parkway Parsippany, NJ 07054
Establishment Registration Number:	2242816
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Date Prepared:	August 12, 2009
Trade/Proprietary Name:	Biomet Phoenix™ Ankle Nail System Biomet® Ankle Arthrodesis Nail
Common/Usual Name:	Intramedullary fixation rod
Classification Name:	Rod, Fixation, Intramedullary and Accessories (21 CFR 888.3020)
Device Panel/Product Code:	Orthopedics HSB

Device Description:
The Biomet Phoenix™ Ankle Nail System is an intramedullary nail system (nails and screws) comprised of Ti-6Al-4V and UHMWPE. The Biomet® Ankle Arthrodesis Nail System is an intramedullary nail system (nails and screws) comprised of T-6Al-4V.

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Indications for Use:
The indications for use for both of these systems have been modified to include the following indications that are denoted with an asterisk(*):

- Avascular necrosis of the talus
- Failed total ankle arthroplasty
- Trauma (malunited tibial pilon fracture)
- Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Revision ankle arthrodesis
- Neuroarthropathy
- Rheumatoid arthritis
- Osteoarthritis
- Pseudoarthrosis
- Post-traumatic arthrosis*.
- Previously infected arthrosis*
- Charcot foot*
- Severe endstage degenerative arthritis*
- Severe defects after tumor resection*
- Pantalar arthrodesis*

The following contraindications are being added to the product labeling. These labeling additions are being made based upon input from surgeons who have reviewed the surgical technique.

The additional contraindications are:

- Dysvascular limb
- Severe longitudinal deformity
- Insufficient plantar heel pad
- Situations where an isolated ankle or subtalar fusion can be performed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Biomet Trauma
% Ms. Margaret F. Crowe
100 Interpace Parkway
Parsippany, New Jersey 07054

AUG 17 2009

Re: K091976
Trade/Device Name: Biomet Phoenix Ankle Nail System and the Biomet Ankle Arthrodesis Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: June 29, 2009
Received: July 1, 2009

Dear Ms. Crowe:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091976

Device Name: Biomet Phoenix™ Ankle Nail System

Biomet® Ankle Arthrodesis Nail

The Biomet Phoenix™ Ankle Nail System and the Biomet® Ankle Arthrodesis Nail are indicated for tibiotalocalcaneal arthrodesis (fusion).

Specific indications include:

1. Avascular necrosis of the talus
2. Failed total ankle arthroplasty
3. Trauma (malunited tibial pilon fracture)
4. Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
5. Revision ankle arthrodesis
6. Neuroarthropathy
7. Rheumatoid arthritis
8. Osteoarthritis
9. Pseudoarthrosis
10. Post-traumatic arthrosis
11. Previously infected arthrosis
12. Charcot foot
13. Severe endstage degenerative arthritis
14. Severe defects after tumor resection
15. Pantalar arthrodesis

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091976