

AUG 26 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS



Kod1782
page 1 of 2

Submitters Name: *aap* Implantate AG
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Germany
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Contact Name: Dipl.-Ing. Christian Abel, Director Quality Management

Name of Device: Biorigid Nail Femur (BNF)

Classification Name: Intramedullary Fixation Rod

Common/Usual Name: Biorigid Femoral Nail System

Proprietary Name: *aap* Biorigid Nail Femur (BNF)

Classification: Class II, Intramedullary Fixation Rod,
CFR Chapter I, Title 21 § 888.3020,
87 J DS #, # 87 H SB #, # 87 H TN

Performance Standards:

Devices are manufactured according to cGMP's, applicable ASTM requirements, and applicable harmonised standards ISO 9001 / EN 46001.

Material Composition:

aap Biorigid Nail Femur components are manufactured of Titanium Alloy (Ti 6Al 4V E.L.I. = ASTM F136)

Intended Use:

aap Biorigid Nail Femur (BNF) is intended to use in fractures of the femoral bone.

The indications are:

- Types of Fractures: Simple closed fractures
Comminuted fractures
Open fractures of first, second or third degree
Crush fractures
- Antegrade Indications: Femur shaft fractures
Distal femur shaft fractures
Pathological fractures, e.g. tumor osteolysis
Periprosthetic femur fracture in the middle to third part with knee replacement in situ
- Retrograde Indications: Supracondylary fractures
Simultaneous nailing of femur and tibia
Distal femur fracture with osteosynthesis or hip prosthesis in situ
Periprosthetic femur fracture at knee arthroplasty
- Borderline Indications: Percondylar femur fracture
Pseudarthrosis (only reamed method)
Osteoporosis



Device Description:

Intramedullary rods are used for the stabilisation of fractures or correction of deformity of long bones with or without interlocking screws. The connection between the nail and the interlocking screw is realised with central holes or grooves. Reamed and unreamed intramedullary nailing and for the femoral bone the antegrade and retrograde entrance are standard methods today.

aap Biorigid Nail Femur (BNF) is the consistent development of the Biorigid Nail Tibia for the femoral bone. The BNF is a full material nail. The interlocking of the nail happens with solid Ø 5.3 mm screws through central holes and grooves.

The central holes on the nail protect against rotational forces. The grooves are designed for interlocking possibility over the whole length of the nail and a defined reduction of the rigidity because of the full material nail.

The BNF permits the execution of different implantation techniques and interlocking with only one nail. Therefore it meets the different injury manners and necessity for individual solutions.

aap Biorigid Nail Femur (BNF) incorporates

- Nail in different diameters
- Interlocking screws in different lengths
- Interlocking nut
- Protection cap in different lengths
- CondyLock
- Accessories, like targeting devices etc.

Predicate Devices for Substantial Equivalence:

aap Implantate AG's Biorigid Nail Femur (BNF) is similar in size, material and intended use to the Howmedica Osteonics Corp. T2 Femoral Nail System (K010801 / K011622 / K014220), Synthes Ti Distal Femoral Nail (K970733), Synthes Proximal Femoral Nail (K970097), Synthes Titanium Unreamed Femoral Nail (K923597), Smith & Nephew Titanium Nail System (K981529), Smith & Nephew Intramedullary Nail System (K983942), DePuy ACE AIM Titanium Supracondylar Nail (K974781), Biomet Titanium Intramedullary Nails (K982953), Biomet Titanium Retrograde Femoral Nail (K013923)

Comparison of Technological Characteristics: *aap* BNF is substantially equivalent to the predicate devices with respect to physical/technical and material characteristics.

Sterilisation Information:

The devices are distributed in non sterile condition.

The instruments and implants provided in non-sterile condition must be decontaminated, cleaned and sterilised prior to each surgery. All packaging materials must be removed.

Recommendations for sterilisation are contained in the package insert.

Note: These devices are sterilised by end users utilizing the approved/outlined guidelines found in the AAMI Guideline "Good Hospital Practice: Steam Sterilisation and Sterility Assurance" and in ANSI/AAMI/ISO 11737 guidelines to achieve the acceptable Sterility Assurance Level (SAL).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 26 2002

AAP Implantate AG
Dipl.-Ing. Christian Abel
Director Quality Management
Lorenzweg 5
12099 Berlin
Germany

Re: K021782

Trade/Device Name: aap Biorigid Nail Femur (BNF)
Regulation Number: 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: JDS
Dated: May 14, 2002
Received: May 30, 2002

Dear Mr. Abel:

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.

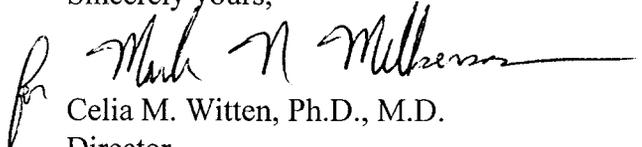
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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" (21 CFR 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 long horizontal flourish extending to the right.

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): K021782

Device Name: BNF

Indications For Use:

Types of Fractures:

Simple Closed Fractures

Comminuted Fractures

Open Fractures of First, Second or Third Degree

Crush Fractures

Antegrade Indications:

Femur Shaft Fractures

Distal Femur Shaft Fractures

Pathological Fractures (e.g. Tumor Osteolysis)

Periprosthetic Femur Fracture in the Middle of Third

Part with Knee Replacement in Situ

Retrograde Indications:

Supracondylary Fractures

Simultaneous Nailing of Femur and Tibia

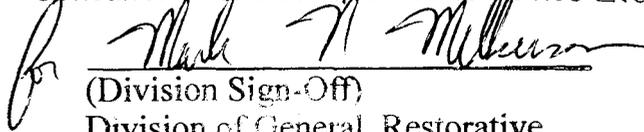
Distal Femur Fracture with Osteosynthesis or

Hip Prosthesis in Situ

Periprosthetic Femur Fracture at Knee Arthroplasty

Borderline Indications: Percondylar Femur Fracture,
(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 K021782

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-9)