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510(k) Summary of Safety and Effectiveness

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[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Contact:

PLUS ORTHOPEDICS
6055 Lusk Blvd.
San Diego, CA 92121
Tel: 858-550-3800 x 2506
Attn: Mr. Hartmut Loch, RAC
Director, Regulatory Affairs

Trade name: SLIM Gliding Nail System

Common name: Compression Hip Nail

Classification name: Appliance, Fixation, Nail/Bl;ade/Plate Combination, Multiple Component § 888.3030, Class II, Product Code: KTT, 87 Orthopedic Device Panel

Predicate Device: FRIEDL Gliding Nail System, K974409 – S/E 2/19/1998

Device Modification Description:

We added the following smaller nails to our predicate device (FRIEDL Gliding Nail System, K974409):
- # 132071 Slim Gliding Nail, 125°, 220 mm, 17 mm / 11 mm ∅
- # 132072 Slim Gliding Nail, 135°, 220 mm, 17 mm / 11 mm ∅
- # 132073 Slim Gliding Nail, 125°, 180 mm, 17 mm / 11 mm ∅,

These 3 nails are narrower than the conventional nails, which 19 mm diameter proximally and 12 mm distally.
- # 132140 Femoral Neck Blade, 75 mm length

In addition, this 75 mm long femoral neck blade has been added to the existing range from 80 mm to 125 mm.

Indications:

The SLIM Gliding Nail System is an all-purpose locking nail system for ensuring primary load stability in:
- pertrochanteric femoral fractures
- subtrochanteric femoral fractures and
- lateral femoral neck fractures.

Internal fixation with the SLIM Gliding Nail System is indicated in all combination injuries involving the lateral femoral neck or trochanter region and femoral shaft fractures. Thanks to its biomechanical characteristics, the SLIM Gliding Nail System is also suitable for medial femoral neck fractures with retention of the head and simple femoral shaft fractures down to the distal metaphysis. Gliding nail fixation can also be used to secure pathological fractures or to provide weight-bearing stability after varus and valgus revision osteotomies of the proximal femur.

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Contraindications: Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, which put the affected limb at risk, bony defects or poor bone quality, which might endanger the stability of the prosthesis, and any concurrent disease, which might interfere with the function of the implant.

Performance data: Biomechanical fatigue tests have been performed on the worst-case model. The test results of the smaller components were equal or better to the predicate and other commercially available devices, and they are sufficient for *in vivo* loading.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2002

Mr. Hartmut Loch, RAC
Director, Regulatory Affairs
PLUS Orthopedics
6055 Lusk Boulevard
San Diego, California 92121-2700

Re: K020240
Trade/Device Name: SLIM Gliding Nail System
Regulation Number: 21 CFR 888.3030
Regulation Name: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
Regulatory Class: II
Product Code: KTT
Dated: January 22, 2002
Received: January 23, 2002

Dear Mr. Loch:

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 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,

for

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

SPECIAL 510(K) DEVICE MODIFICATION
SLIM Gliding Nail System
January 22, 2002

510(k) Number: K020240

Device Name(s): SLIM Gliding Nail System

Indications for Use:

The SLIM Gliding Nail System is an all-purpose locking nail system for ensuring primary load stability in:

- pertrochanteric femoral fractures
- subtrochanteric femoral fractures and
- lateral femoral neck fractures.

Internal fixation with the SLIM Gliding Nail System is indicated in all combination injuries involving the lateral femoral neck or trochanter region and femoral shaft fractures. Thanks to its biomechanical characteristics, the SLIM Gliding Nail System is also suitable for medial femoral neck fractures with retention of the head and simple femoral shaft fractures down to the distal metaphysis. Gliding nail fixation can also be used to secure pathological fractures or to provide weight-bearing stability after varus and valgus revision osteotomies of the proximal femur.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K020240

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional format 1-2-96)