



510(k) Summary of Safety and Effectiveness Information
(as required by 807.92c), prepared by Hartmut Loch, President of
HHL Consulting for PLUS Orthopedics in San Diego, California
November 10, 1997

Trade name: FRIEDL Gliding Nail System

Common name: Compression Hip Nail

Classification name: Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component, 87KTT, Regulation Number 888.3030.

Description: The FRIEDL Gliding Nail System is an all-purpose locking nail system for primary load stability in pertrochanteric femoral fractures, subtrochanteric femoral fractures, and lateral femoral neck fractures. This system consists of several sizes of intramedullary nails, femoral neck blades, and distal locking pins. The Friedl Gliding Nail System is made of Wrought High Nitrogen Stainless Steel according to ISO 5832-9.

Indications: The Friedl 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 long Friedl Gliding Nail is indicated in all combination injuries involving the lateral femoral neck or trochanter region and femoral shaft fractures. Thanks to its biomechanical characteristics, the Friedl 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.

Comparable Features to Predicate Device: The FRIEDL Gliding Nail System is comparable to the Gliding Nail from Encore Orthopedics, Inc., which was cleared for marketing by FDA on July 13, 1995 (K-951809).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1998

Mr. Hartmut Loch
President
HHL Consulting
Representing PLUS Orthopedics
835 Cortez Lane
Foster City, California 94404

Re: K974409
Trade Name: FRIEDL Gliding Nail System
Regulatory Class: II
Product Code: KTT
Dated: November 10, 1997
Received: November 24, 1997

Dear Mr. Loch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

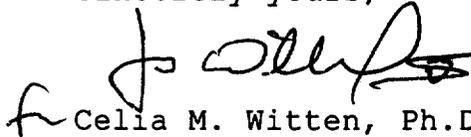
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K974409Device Name: FRIEDL GLIDING NAIL SYSTEM

Indications for Use:

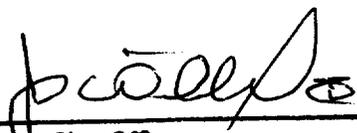
The Friedl Gliding Nail System is an all-purpose locking nail system for ensuring primary load stability in:

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

Internal fixation with the long Friedl Gliding Nail is indicated in all combination injuries involving the lateral femoral neck or trochanter region and femoral shaft fractures. Thanks to its biomechanical characteristics, the Friedl 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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K974409

Prescription Use OR Over-The-Counter Use
 (Per 21 CFR 801.109)

(Optional Format 1-2-96)