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510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: December 1, 2003

Applicant: PLUS Orthopedics
6055 Lusk Boulevard
San Diego, CA 92121-2700

Telephone: 888-741-7587
Fax: 888-741-4002

Device Name:	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
Device Trade Name:	SLIM Gliding Nail System
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	21 CFR 888.3030
Product Code:	KTT
Original Predicate Device:	SLIM Gliding Nail System, K020240 The indications for use have not changed and are identical to the predicate device.
Registration Number:	2086141
Owner Operator Number:	9034096

Device Description:

The SLIM Gliding Nail Systems designed for internal fixation in all combination injuries involving the lateral femoral neck or trochanter region and femoral shaft fractures. The 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.

Indications for Use:

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

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- 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 medical 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.

Comparison to the Original Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the SLIM Gliding Nail System, K020240

Regulatory Class: II
Product Code: KTT

Comparison of original PLUS Orthopedics SLIM Gliding Nail System to the new configuration.

Item	*Original PLUS Product*	*Proposed modified product*
Product Name	SLIM Gliding Nail System	SLIM Gliding Nail System
Use	Single use	Single use
Fixation	Compression Hip Nail	Compression Hip Nail
Constraint	Constrained	Constrained
Material	Stainless Steel	Stainless Steel
Sizes	The blade comes in 11 sizes	The blade comes in 11 sizes
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	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

femoral shaft fractures. Thanks to its biomechanical characteristics, the SLIM Gliding Nail System is also suitable for medical 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.	and femoral shaft fractures. Thanks to its biomechanical characteristics, the SLIM Gliding Nail System is also suitable for medical 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.

The only design modification to the SLIM Gliding Nail System is the removal of the collar from the gliding blade.

Summary:

The device and the predicate device have similar design characteristics and intended use. The modified device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2003

Mr. Neil Delaney
Plus Orthopedics, Inc.
6055 Lusk Boulevard
San Diego, California 92121-2700

Re: K033763
Trade/Device Name: SLIM Gliding Nail System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Codes: KTT
Dated: December 1, 2003
Received: December 2, 2003

Dear: Mr. Delaney:

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 (301) 594-4659. 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,

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

510 (k) Number (If Known): K033763

Device Name: 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 medical 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)

Prescription Use X or Over the counter use _____

for Mark N Milhous

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

510(k) Number K033763