

4/1/99

K990322

5. 510(K) Summary

**Pioneer Surgical Technology
510(K) Notification Summary
For
Perry Nail**

Administrative Information

Manufacturer Identification and Sponsor:

Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855-1781
Telephone: 906-226-9909
FAX: 906-226-9932

Official Contact:

Burns Severson
Vice President, Regulatory Affairs/Quality Assurance

Date Prepared:

Device Identification

Proprietary Name:
Perry Nail

Common Name:
Humeral Nail

Classification Name and Reference:
Intramedullary Fixation Rod
Regulation Number: 21 CFR 888.3020, ClassII
Classification Number: 87HSB

Devices on which substantial equivalence is claimed:

Device Description

The Perry nail geometry consists of a tubular proximal region and a distal blade region. The tubular proximal region displays a 10° lateral bend and an upper portion of the tube with internal threads created to house one or two bone screw locking cannulated set screws. The device is designed to accept transfixing screws. The two proximally located transfixing screw holes allow ± 15° anterior/posterior inclination of either 6.5mm cancellous or 4.5mm cortical screws into the humeral head and trochanter fragments. A summary of the nail configurations to be offered is displayed in Table 1.

Table 1: Perry Nail Configurations

Proximal Ø (mm)	Distal Ø (mm)	Blade Configurations		Lengths (mm)
11	8	Slot	No Slot	195 to 270 x 15
11	9	Slot	No Slot	225 to 300 x 15
11	10	Slot	No Slot	240 to 315 x 15
11	11	Slot	No Slot	240 to 315 x 15
12	12	Slot	No Slot	240 to 315 x 15

The instrumentation includes the following components for inserting/ removing the nail and guiding the designated screws through the nail. The Nail Locking Bolt slips inside the Angle Arm Base engaging the proximal threads of the nail in combination with the tabs and slot engagement between the Angle Arm Base and the nail. A Combination Wrench tightens the head of the Nail Locking Bolt. If some insertion or extraction force is necessary, the impactor slide is passed over the impactor guide followed by the engagement of the guide with the internal threads of the Nail Locking Bolt. The Targeting Guide is positioned on the Angle Arm Bases' locating pins and secured to it by the Targeting Guide Locking Bolt.

Intended Use

The Perry Nail device is indicated for stabilizing humeral fractures.

Technological Characteristic Compared to Predicate Device

Performance Data

The Perry nail device was predicated on the use of the Orthologic Orthonail.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 1999

Mr. Burns Severson
Senior Vice President
Regulatory Affairs/Quality Assurance
Pioneer Laboratories
375 River Park Circle
Marquette, Michigan 49855-1781

Re: K990322
Trade Name: Perry Humeral Nail
Regulatory Class: II
Product Code: HSB
Dated: February 1, 1999
Received: February 2, 1999

Dear Mr. Severson:

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.

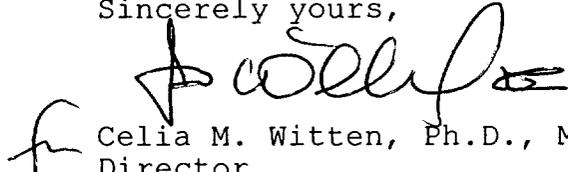
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 premarket 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.

Page 2 - Mr. Burns Severson

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

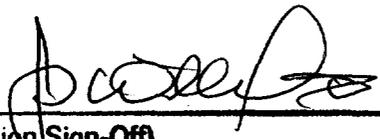
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Pioneer Surgical Technology

Perry Nail

Indications for Use

The Perry Nail device is indicated for use in stabilizing humeral fractures.



(Division Sign-Off)
Division of **General Restorative Devices** K990322
510(k) Number _____

Prescription Use _____
(Per 21 CFR 801.109)