510(k) Summary

Date
August 14, 2003

SEP 1 0 2003

K032548
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Submitter
PLUS Orthopedics
6055 Lusk Blvd
San Diego, CA 92121

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Intramedullary nail

Classification name
Rod, Fixation, Intramedullary and Accessories per 21 CFR section 888.3020.

Equivalent Device
The IP-XS Compression Nail is similar in materials, design and indications as the Small Bone Nail (Accumed K031438) and SST Small Bone Locking Nail (Biomet).

Device Description
The IP-XS Compression Nail system is for bones with small canals as the nail comes in diameters of 3.5mm and 4.5mm. They have a circular cross section with multiple transverse holes for interlocking components. The two proximal transverse holes are elongated to allow the interlocking component to move axially and apply compression to the bone fragments. The proximal end has an internal axial threaded hole to receive a compression screw. Threaded Kirschner wires Ø2.0mm and Ø1.6mm are used as the interlocking components.

Intended Use
The IP-XS Compression Nail System is inserted into the medullary canal of long bones for the alignment, stabilization and fixation of fractures caused by disease or trauma; the fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity; and for arthordesis.

Summary Nonclinical Tests
Cantilever testing, simulating loading that might be seen when this device is used for ankle fractures, was performed as well as validated FEA analysis. This testing indicates that the IP-XS Compression Nail will support the *in-vivo* loads expected to be seen for this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2003

Mr. J.D. Webb
PLUS Orthopedics
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K032548
Trade/Device Name: IP-XS Compression Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: August 14, 2003
Received: August 18, 2003

Dear Mr. Webb:

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 Miriam C. Provost

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): K032548

Device Name: IP-XS Compression Nail System

Indications for Use:

IP-XS Compression Nail System
Indications for Use

The IP-XS Compression Nail System is inserted into the medullary canal of long bones for the alignment, stabilization and fixation of fractures caused by disease or trauma; the fixation of long bones that have been surgically prepared (osteotomy) for correction of deformity; and for arthordesis.

(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, Neurological and Restorative Devices

510(k) Number_____

Prescription Use ____
(per 21 CFR 801.109) OR Over-the-Counter Use ____

(Optional format 1-2-96) _____

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032548