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K033289

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510(k) Summary of Safety and Effectiveness
Jet-X® Half Pins

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	October 10, 2003
Contact Person:	David Henley Senior Clinical/Regulatory Affairs Specialist Tel: (901) 399-6487 Fax: (901) 398-5146
Proprietary Name:	**Jet-X Half Pins**
Common Name:	Half Pins
Classification Name and Reference:	Smooth or threaded metallic bone fixation fastener, 21 CFR 888.3040, Class II
Device Product Code and Panel Code:	JDW/Orthopedics/87

Device Description:
The Jet-X Half Pin is a modification of the Jet-X Half Pin that was cleared for market under K023921. This submission describes measures taken to implement an alternate supplier for application of the hydroxyapatite (HA) coating.

Intended Use:
The Jet-X Half Pin is intended to be used with an external fixation system for fracture fixation (open and closed); pseudoarthrosis or nonunion of long bones; limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

Technological Characteristics:
The principles of operation for the Jet-X Half Pin are identical to the Jet-X Half Pin cleared under K023921. Both are half pins that are used with external fixation systems for fracture fixation (open and closed) and other indications listed above. The hydroxyapatite (HA) coating applied to the subject device is equivalent to the HA coating currently used on Smith & Nephew's Jet-X Half Pin (K023921). The design and material used in the Jet-X Half Pin has the same technological characteristics as one or more of the predicate devices.

Substantial Equivalence Information:
The dimensional characteristics, design, material type, principle of operation, indications for use and intended use of the subject Jet-X Half Pin are identical to the Jet-X Half Pin cleared under K023921. The HA coating is identical to the coating used on Smith & Nephew's Jet-X Half Pin (K023921).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2004

Mr. David Henley
Senior Clinical/Regulatory Affairs Specialist
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K033289
Trade/Device Name: Jet-X® HA Coated Half Pin
Regulation Number: 21 CFR 888.3040
Regulation Names: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Codes: JDW
Dated: December 12, 2003
Received: December 15, 2003

Dear Mr. Henley:

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

Indications for Use Statement

Jet-X® HA Coated Half Pin

510(k) Number (if known): K033289

Device Name: **Jet-X® HA Coated Half Pin**

Indications for Use:

The Jet-X HA Coated Half Pin is intended to be used with an external fixation system for fracture fixation (open and closed); pseudoarthrosis or nonunion of long bones; limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformity; correction of segmental bony or soft tissue defects; and joint arthrodesis.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

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

K033289

(510(k) Number)