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510(k) Summary of Safety and Effectiveness
Jet-X® Bar System Clamps, Bars and Posts – MR Conditional

Submitted by: Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

MAR - 7 2008

Date: August 8, 2007

Contact Person: David Henley
Regulatory Affairs Project Manager

Proprietary Name: **Jet-X® Bar System Clamps, Bars and Posts – MR Conditional**

Common Name: External Fixation Accessories
Classification Name and Reference: Smooth or threaded metallic bone fixation fastener, 21 CFR 888.3040, Class II
Device Product Code and Panel Code: KTT / Orthopedics / 87

Device Description:
External fixation devices, such as the Jet-X® Bar System Clamps, Bars and Posts – MR Conditional devices described herein, are specifically designed components to be used in the management of bone fractures and reconstructive, as well as corrective, orthopedic surgery. Devices include Jet-X System Clamps, Bars, and Posts. The materials used in their manufacture are chosen to address a wide range of applications. These devices have been designed to allow for the appropriate amount of rigidity and stability. The devices described herein are made from non-magnetic materials and are intended for use in the MR environment.

Intended Use:
The devices described herein are intended to be used on adults or pediatric patients as required and are intended to be used for fracture fixation (open and closed); post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis or non-union 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; joint arthrodesis; and management of comminuted intra-articular fractures of the distal radius. Jet-X® Bar System Clamps, Bars and Posts – MR Conditional are for single use only.

Technological Characteristics:
The principle of operation of these devices is identical to that of the predicates. There are no changes in intended use, performance specifications or method of operation. These non-magnetic MR Conditional devices utilize stainless steel, titanium, and aluminum materials and technological characteristics that are very similar when compared to the predicate devices.

Substantial Equivalence Information:
Documentation is provided in this premarket notification that demonstrates that Jet-X® Bar System Clamps, Bars and Posts – MR Conditional devices are substantially equivalent to other legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Mr. David Henley
Regulatory Affairs Project Manager
1450 Brooks Road
Memphis, Tennessee 38116

MAR - 7 2008

Re: K072212
Trade/Device Name: Jet-X Bar System Clamps, Bars and Posts-MR Conditional
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: February 6, 2008
Received: February 7, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Premarket Notification
Indications for Use Statement

Jet-X® Bar System Clamps, Bars and Posts – MR Conditional

510(k) Number (if known):

Device Name: Jet-X® Bar System Clamps, Bars and Posts – MR Conditional

Indications for Use:

Jet-X Bar External Fixation System components are intended to be used on adults or pediatric patients as required and are intended to be used for fracture fixation (open and closed); post-traumatic joint contracture which has resulted in loss of range of motion; fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction; pseudoarthrosis 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; infected fractures or non-unions; joint arthrodesis; and management of comminuted intra-articular fractures of the distal radius.

Jet-X® Bar System Clamps, Bars and Posts – MR Conditional components are for single use only.

Prescription Use __X__ (Per 21 CFR 801.109) OR Over-the-Counter Use _____ (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mxm

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

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