K050849

510(k) Summary of Safety and Effectiveness

Contact Person and Address MAY - 4 2005 **Date of Summary:** April 1, 2005

David Henley
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Name of Device: HA Coated Lag Screws
Common Name: Lag Screws

Device Description
HA (Hydroxylapatite) Coated Lag Screws are large metallic screw devices that are used in conjunction with *Compression Hip Screw Systems* and *Intramedullary Hip Screw Systems* to obtain purchase inside the femoral head or condyles to help provide support for compression of the fracture. HA Coated Lag Screws are available in various sizes made from either 316L stainless steel or Titanium-6Al-4V metal materials.

Device Classification
21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories - Class II

Mechanical and Clinical Data
A review of the mechanical test data indicated that the HA Coated Lag Screws are equivalent to devices currently used clinically and are capable of withstanding expected *in vivo* loading without failure.

Indications for Use
The Hydroxyapatite (HA) Coated Lag Screws are used with the *Compression Hip Screw Systems* and *Intramedullary Hip Screw* (IMHS) Systems in adult patients for the following indications:

Compression Hip Screws/ IMHS

1. Intracapular fractures of the femoral neck. (For high subcapsular fractures it may be more prudent to select a prosthesis in lieu of internal fixation to reduce the risk of a nonunion or avascular necrosis of the femoral head.)
2. Trochanteric or subtrochanteric fractures with appropriate additional postoperative precautions about weight bearing and more than sedentary activity.
3. Osteotomies for patients with diseases or deformities of the hip.
4. Hip arthrodesis.
5. Supracondylar fractures and distal femoral fractures using a supracondylar plate.
6. Ipsilateral femoral shaft/neck fractures (long IMHS only).

Substantial Equivalence Information
Substantial equivalence of the HA Coated Lag Screw is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – Smith & Nephew Trauma Internal Fixation System (K993289), Smith & Nephew HA Global Taper Tapered (Synergy) Hip System (K970337), and Smith & Nephew Jet-X HA Coated Half Pins (K033289 and K023921).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

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

Re: K050849
Trade/Device Name: HA Coated Lag Screws
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: April 1, 2005
Received: April 4, 2005

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): _____

Device Name: HA Coated Lag Screws

Indications for Use:

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Compression Hip Screws/ IMHS

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6. Ipsilateral femoral shaft/neck fractures (long IMHS only)

HA Coated Lag Screws are for single use only.

Prescription Use X and/or **Over-The-Counter Use** _____
(Part 21 CFR 801, 109) (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)

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

510(k) Number K050849