DEC 20 1999

K993289

Summary of Safety and Effectiveness
Smith & Nephew, Inc.
Trauma Internal Fixation System

Substantial Equivalent Information

The ***Trauma Internal Fixation System*** is similar to the following trauma systems:

1. IMHS Hip Screw Systems – Smith & Nephew
2. Titanium Classic Compression Hip Screw System - Smith & Nephew
3. Osteotomy/ Blade Plates - Smith & Nephew
4. Medoff Sliding Plate - Wright Medical Technology
5. Biomet Compression Hip Screw System - Biomet Medical Products
6. Vari-Angle Hip System – Biomet
7. ACE Cannulated Hip Screw System – ACE
8. Alta Modular Trauma System – Howmedica
9. NoLok/Keyed Compression Hip Screw System – DePuy
10. Free-Lock Femoral Fixation System – Zimmer
11. Dynamic Hip/Condylar Screw System – Synthes
12. Synthes Femoral Nail System
13. Howmedica Gamma Locking Nail System
14. Angled/Condylar/Osteotomy Blade Plates – Synthes

All of the devices listed above are indicated for the same use as compression hip screw systems, and are similar in design to the ***Trauma Internal Fixation System***. The safety and effectiveness of the ***Trauma Internal Fixation System*** is based on the long history of use of these devices in the market place.

Device Description

The ***Compression Hip Screw*** is composed of a plate, lag screw, compression screw,and bone screws. The Intramedullary Hip Screw is composed of a intramedullary nail, lag screw, compression hip screw, centering sleeve, set screw and bone screws. In addition, there are Compression Hip Screw Barrel Plates, Supracondylar Barrel Plates, Blade Plates, Condylar Blade Plates, Intramedullary Hip Screws, Lag Screws and Compression Hip Screws. There are various accessory items used with the Compression Hip Screw System, such as: Set Screws, Nail Caps, Centering Sleeves, Self-Tapping Bone Screw, Lag Screw Clips, Bone Bolts, and Bone Screws.

The above devices and accessories are made from either Stainless Steel (ASTM F-138, ISO 5832/1) or Titanium (Ti-6Al-4V) alloy (ASTM F-1472, ISO 5832-3). Nail caps are made from ultra high density molecular weight polyethylene (ASTM F-648).

Indications for Use

The ***Trauma Internal Fixation System*** is used for fracture fixation in the proximal and distal regions of the femur. In particular, indications for use in adult and pediatric patients are as follows:

Adult indications:

1. Intracapsular 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 (IMHS only).

Pediatric indications:

1. Congenital coxa vara.
2. Congenital dislocation of the hip.
3. Subluxation or dislocation secondary to neurologic disorders such as cerebral palsy, myelomenigocele, poliomyelitis, etc. Usually valgus-anteversion deformities.
4. Coxa plana (Legg-Calve-Perthes disease) for containment of the head completely within the acetabulum.

Technological Characteristics:

Trauma Internal Fixation System are similar to the predicate devices listed above in material, design, function, and use, and have similar technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 20 1999

Ms. Janet Johnson Green
Manager, Clinical and Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K993289
Trade Name: Trauma Internal Fixation System
Regulatory Class: II
Product Codes: KTT
Dated: October 1, 1999
Received: October 1, 1999

Dear Ms. Green:

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 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). 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 requirements, 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.

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) 594-4595. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications Enclosure

510(k) Number (if known): K993289

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

Concurrence of CDRH, Office of Device Evaluation (ODE) NRO for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993289

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use ____
(Optional Format 1-2-96)