

DEC - 9 1999

K993106

510(k) Summary
Smith & Nephew Bone Plate System

Submitter's name: Smith & Nephew, Inc., Orthopaedic Division
Submitter's address: 1450 Brooks Road, Memphis, TN 38116
Submitter's telephone number: 901/399-5153
Contact person: Janet Johnson Green
Date summary prepared:
Trade or proprietary device name: Smith & Nephew Bone Plate System (bone plates, bone screws and accessories)

Common or usual name: Bone Plates, Bone Screws, and Accessories
Classification name: Title 21 CFR 888.3030 (Plates and Accessories)
Single/multiple component metallic bone fixation appliances and accessories
Title 21 CFR 888.3040 (Screws)
Smooth or threaded metallic bone fixation fastener

Device Class: Class II
Device Product Code and Panel Code: 87HRS - Plate
87HWC - Screw
Panel: Orthopaedics/87

Substantially Equivalent, Legally Marketed Predicate Devices:

Richards Bone Plates and Bone Screws (Smith & Nephew [f/k/a Richards Medical Company])
Osteo* Bone Plates and Bone Screws (Smith & Nephew)
Titanium Plates (Synthes)
Basic Screw Set (Synthes)
ECT Plates and Screws (Zimmer)
TiMAX™ Large Fragment System (DePuy)
TiMAX™ Bone Screws (DePuy)

Subject device description:

Smith & Nephew Bone Plates, Bone Screws, and Accessories like the predicate devices, include various sizes of implants to accommodate the individual requirements of patient anatomy.

Subject device intended use:

Smith & Nephew Bone Plates, Bone Screws, and Accessories are indicated for pelvic, small and long bone fracture fixation.

Smith & Nephew Bone Screws are indicated for long bone fracture fixation.

Smith & Nephew Bone Plates, Bone Screws, and Accessories are for single use only.

Technological Characteristics:

Smith & Nephew Bone Plates, Bone Screws, and Accessories are similar to legally marketed devices listed above in that all of these devices are indicated for pelvic, long, and small bone fracture fixation, are manufactured from similar or like materials, and are similar in technological characteristics.

*Osteo was formerly owned by Smith & Nephew (formerly Richards Medical Company). Smith & Nephew currently distributes devices manufactured by Osteo.



DEC - 9 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K993106
Trade Name: Smith & Nephew Bone Plate System
Regulatory Class: II
Product Codes: HRS and HWC
Dated: September 16, 1999
Received: September 17, 1999

Dear Ms. Johnson 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 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 (Pre-market 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 requirement, 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) 594-4659. 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" (21 CFR 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/dsmamain.html>".

Sincerely yours,



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

Enclosure

510(k) Number (if known): K993106
Device Name: *Smith & Nephew Bone Plate System*

Indications for Use:

The *Smith & Nephew Bone Plate System* is used for adult or pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

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

Concurrent of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993106

Prescription Use
(Per 21 CFR 601.109)

OR

Over-The-Counter Use