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510(k) Summary of Safety and Effectiveness

PERI-LOC™ Periarticular Locked Plating System

Volar Distal Radius Locking Plate for the Upper Extremity - ASTM F139 Material Change

Submitted By:	Smith & Nephew, Inc., Orthopaedic Division 1450 Brooks Road Memphis, TN 38116 JUN 18 2008
Date:	February 13, 2008
Contact Person:	Laura Sejnowski, Regulatory Affairs Specialist Tel: (901) 399-5349 Fax: (901) 399-1557
Proprietary Name:	**PERI-LOC™ Periarticular Locked Plating System -** ***Volar Distal Radius Locking Plate for the Upper Extremity*** ***ASTM F139 Material Change***
Common Name:	Bone Plates and Bone Screws
Classification Name and Reference:	21 CFR 888.3030, single/multiple component metallic bone fixation appliances and accessories - Class II
Device Product Code and Panel Code:	HRS, HWC / Orthopedics / 87

Device Description:

Volar Distal Radius Locking Plates for the Upper Extremity manufactured from ASTM F139 material are line additions to the PERI-LOC™ Periarticular Locked Plating System cleared under K051735 and K061352. Like the predicate devices listed below, the subject components include various sizes of contoured locking bone plates and locking/non-locking bone screws made from stainless steel. PERI-LOC™ locking bone plates and locking bone screws incorporate a screw-to-plate locking feature which forms a locked, fixed angle construct to aid in holding fracture reduction.

Intended Use:

The PERI-LOC™ Periarticular Locked Plating System can be used for adult patients as well as patients with osteopenic bone. PERI-LOC™ bone plates and screws are indicated for fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.

Technological Characteristics:

PERI-LOC™ Volar Distal Radius Plates manufactured from ASTM F139 material are similar to legally marketed devices listed below in that they share similar indications for use, are manufactured from similar materials, and incorporate similar technological characteristics.

Substantial Equivalence Information:

When compared to the predicate devices listed below, substantial equivalence is based on similarities in design features, overall indications for use, and material composition.

- PERI-LOC™ Periarticular Locked Plating System for the Upper Extremity – K051735
- PERI-LOC™ Periarticular Locked Plating System for the Upper Extremity Device Modifications – K061352
- Smith & Nephew Locked Plating System (PERI-LOC™ Periarticular Locked Plating System) – K033669
- PERI-LOC™ Periarticular Locked Plating System VLP Plates/Screws – K071563

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Orthopaedic Division
Ms. Laura Sejnowski
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, TN 38116

JUN 18 2008

Re: K081106
Trade/Device Name: Peri-Loc™ Periarticular Locked Plating System – Volar Distal Radius Locking Plate for the Upper Extremity
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: May 15, 2008
Received: May 19, 2008

Dear Ms. Sejnowski:

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.

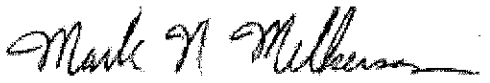
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its 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

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K081106

Device Name: PERI-LOC™ Periarticular Locked Plating System –
Volar Distal Radius Locking Plate for the Upper Extremity - ASTM F139 Material Change

Indications for Use:

The PERI-LOC Periarticular Locked Plating System can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC bones plates and screws are indicated for fixation of pelvic, small and long bone fractures, including those of the tibia, fibula, femur, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, radius, calcaneus, and clavicle.

Components in the PERI-LOC™ Periarticular Locked Plating System 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)

Neil R Ogden for mkm
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081106