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510(k) Summary of Safety and Effectiveness

PERI-LOC™ Periarticular Locked Plating System

VLP Locking Bone Plates and Locking/Non-Locking Bone Screws

Submitted By:	Smith & Nephew, Inc., Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	June 6, 2007 AUG - 8 2007
Contact Person:	David Henley, Regulatory Affairs Project Manager Tel: (901) 399-6487 Fax: (901) 399-1557
Proprietary Name:	**PERI-LOC™ Periarticular Locked Plating System - *VLP Locking Bone Plates & Screws***
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:
PERI-LOC™ Periarticular Locked Plating System – VLP Plates and Screws are line additions to the PERI-LOC™ Periarticular Locked Plating System cleared under K062216. Like the predicate devices listed below, the subject components include various sizes of contoured and straight, locking bone plates and locking/non-locking bone screws made from stainless steel. PERI-LOC™ VLP locking bone plates and locking/non-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:
PERI-LOC™ Periarticular Locked Plating System VLP Plates and Screws can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC™ contoured VLP Plates and Screws are indicated for partial articular fractures (AO/OTA Fracture Classification Type B) of the distal and proximal tibia and for fracture fixation of the fibula. PERI-LOC™ VLP One-Third Tubular Locking Plates are indicated for fixation of fractures, non-unions, and osteotomies of the medial malleolus, fibula, distal ulna, olecranon, calcaneus and metatarsals.

Technological Characteristics:
Components comprising **PERI-LOC™ Periarticular Locked Plating System – VLP Plates and Screws** 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 – K062216
- PERI-LOC™ Periarticular Locked Plating System – K033669
- PERI-LOC™ Periarticular Locked Plating System – K051735
- Smith & Nephew Bone Plate System (TC-100 Plating and Screw System) - K993106
- Synthes One-Third Tubular DCL Plate – K011335

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

AUG - 8 2007

Re: K071563
Trade/Device Name: PERI-LOC Periarticular Locked Plating System – *VLP Locking Bone Plates and Locking/Non-locking Bone Screws*
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: June 6, 2007
Received: June 7, 2007

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.

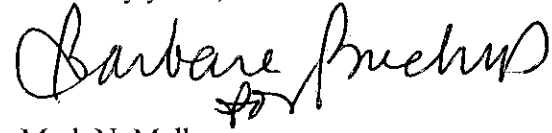
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K071563

Device Name: PERI-LOC® Periarticular Locked Plating System -
VLP Locking Bone Plates and Locking/Non-locking Bone Screws

Indications for Use:

PERI-LOC® Periarticular Locked Plating System VLP Plates and Screws can be used for adult and pediatric patients, as well as patients with osteopenic bone. PERI-LOC® contoured VLP Plates and Screws are indicated for partial articular fractures (AO/OTA Fracture Classification Type B) of the distal and proximal tibia, and for fracture fixation of the fibula. PERI-LOC® VLP One-Third Tubular Locking Plates are indicated for fixation of fractures, non-unions and osteotomies of the medial malleolus, fibula, distal ulna, olecranon, calcaneus and metatarsals.

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)

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

510(k) Number K071563