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510(k) Summary of Safety and Effectiveness
PERI-LOC™ Locking Hole Inserts and Cable Accessories

Submitted By:	Smith & Nephew, Inc., Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	May 4, 2010
Contact Person:	Laura Medlin, Regulatory Affairs Specialist Tel: (901) 399-5349 Fax: (901) 398-5146
Proprietary Name:	**PERI-LOC™ Locking Hole Inserts and Cable Accessories**
Common Name:	Locking Bone Plate Accessories
Classification Name and Reference:	21 CFR 888.3040, smooth or threaded metallic bone fixation fastener, Class II
Device Classification for Predicate Devices:	21 CFR 888.3040, smooth or threaded metallic bone fixation fastener, Class II
Device Product Code and Panel Code:	Panel: Orthopedics / 87 Product Code: HWC

MAY - 4 2010

Device Description:
Subject of this premarket notification are PERI-LOC™ Locking Hole Inserts and Cable Accessories. The PERI-LOC Locking Hole Inserts and Cable Accessories are line additions to the PERI-LOC Periarticular Locked Plating System cleared under K033669, K051735, K061352, K072818, and K082516. The subject Locking Hole Inserts and Cable Saddles are accessory components that may be used in conjunction with various PERI-LOC locking bone plates for the upper and lower extremities. The subject devices are made from 316L stainless steel.

When compared to the predicate PERI-LOC Screw Hole Plug and Cable Saddles, the subject PERI-LOC Locking Hole Inserts and Cable Saddles have been modified as follows:

- Designed to be used independently or in conjunction with one another
- Addition of a Hexalobular drive feature
- Addition of a 3.5mm Locking Hole Insert

The subject devices are available in the following size ranges:

Device Type	Available Drive Feature
3.5mm Locking Hole Insert	Hex *or* Hexalobular
4.5mm Locking Hole Insert	Hex *or* Hexalobular
Short Cable Saddle	Hex *or* Hexalobular
Tall Cable Saddle	Hex *or* Hexalobular

Intended Use:
PERI-LOC Locking Hole Inserts and Cable Accessories are intended for use with existing PERI-LOC Periarticular Locked Plating Systems and their cleared indications for use as listed below:

The PERI-LOC Periarticular Locked Plating System including Locking Hole Inserts and Cable Accessories can be used for adult and pediatric 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.

PERI-LOC Periarticular Locked Plating System Proximal Femur Bone Plates, Bone Screws, Locking Hole Inserts and Cable Accessories can be used for adult patients as well as patients with osteopenic bone. PERI-

LOC Proximal Femur Locking Bone Plates, Bone Screws, Locking Hole Inserts and Cable Accessories are indicated for fractures of the trochanteric region including simple intertrochanteric, reverse oblique trochanteric, transverse trochanteric, complex multi-fragmentary, and fractures with medial cortex instability; proximal femur fractures combined with ipsilateral shaft fractures; pathological fractures of the proximal femur including metastatic fractures; proximal femur osteotomies; fixation of fractures in osteopenic bone; fixation of nonunions and malunions; basi/transcervical femoral neck fractures; subcapital femoral neck fractures; and subtrochanteric femur fractures.

Components in the PERI-LOC Periarticular Locked Plating System are for single use only.

Technological Characteristics:
The **PERI-LOC Locking Hole Inserts and Cable Accessories** are similar to legally marketed devices listed below in that they share similar indications for use, are manufactured from identical material, and incorporate similar technological characteristics.

Performance Data
To further support a determination of substantial equivalence, pre-clinical testing was conducted on the subject devices. Pre-clinical testing included *four point bend fatigue testing* of plate constructs with appropriate accessory devices.

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

- Smith & Nephew Locking Bone Plate System (PERI-LOC Periarticular Locked Plating System) – K033669
- PERI-LOC Locking Bone Plates and Locking Bone Screws for the Upper Extremity – K051735
- PERI-LOC Periarticular Locked Plating System for the Upper Extremity – K061352
- PERI-LOC Periarticular Locked Plating System Proximal Femur Plates, Screws, and Cable Accessories – K072818
- PERI-LOC Periarticular Locked Plating System Hexalobular Bone Screws – K082516

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew Inc.
% Laura Medlin
1450 Brooks Rd.
Memphis, Tennessee 38116

MAY - 4 2010

Re: K100325
Trade/Device Name: PERI-LOC Locking Hole Inserts and Cable Accessories
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 1, 2010
Received: February 4, 2010

Dear Ms. Medlin:

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 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.

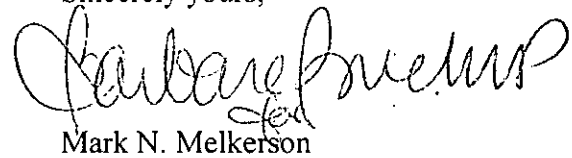
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K100325 (pg 1/1)

Device Name: PERI-LOC™ Locking Hole Inserts and Cable Accessories

Indications for Use:

PERI-LOC Locking Hole Inserts and Cable Accessories are intended for use with existing PERI-LOC Periarticular Locked Plating Systems and their cleared indications for use as listed below:

The PERI-LOC Periarticular Locked Plating System including Locking Hole Inserts and Cable Accessories can be used for adult and pediatric 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.

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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)

for MAM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100325