510(k) Summary of Safety and Effectiveness

K112406 (pg 1/2)

PERI-LOC™ Periarticular Locked Plating System
Proximal Femur Locking Bone Plates

NOV 14 2011

Submitted By:

Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

Date:

August 19, 2011

Contact Person:

David Henley, Regulatory Affairs Project Manager
Tel: (901) 399-6487 Fax: (901) 566-7079

Proprietary Name:

PERI-LOC™ Periarticular Locked Plating System - *Proximal Femur Locking Bone Plates*

Common Name:

Bone Plates

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 / Orthopedics / 87

Device Description:

The subject **PERI-LOC™ Periarticular Locked Plating System – Proximal Femur Locking Bone Plates** manufactured from titanium material have undergone a design modification when compared to devices cleared under K072818. Like the predicate devices, the subject devices include various lengths of contoured, locking bone plates made from titanium material. PERI-LOC™ Proximal Femur locking bone plates incorporate a screw-to-plate locking feature which forms a locked, fixed angle construct to aid in holding fracture reduction. The subject implant devices will be available in the following configurations:

Device Type	Devices Available With the Following Number of Individual Locking Screw Holes Per Plate
PERI-LOC 4.5mm Lateral Proximal Femur Locking Plate, LH	2, 4, 6, 9, 12, 15 or 18
PERI-LOC 4.5mm Lateral Proximal Femur Locking Plate, RH	2, 4, 6, 9, 12, 15 or 18

Intended Use:

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

Technological Characteristics:

Components comprising **PERI-LOC™ Periarticular Locked Plating System – Proximal Femur Locking Bone Plates** are similar to legally marketed devices listed below in that they share identical or similar indications for use, are manufactured from titanium material (i.e. devices cleared under K072818), and incorporate identical or similar technological characteristics.

Substantial Equivalence Information:

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

- PERI-LOC™ Proximal Femur Locking Bone Plates (Bone Screws and Cable Accessories) - K072818
- (Smith & Nephew) Trauma Internal Fixation System (TC-100 Blade Plates) - K993289

To further support a determination of substantial equivalence, pre-clinical bench testing was conducted on the subject devices (that have undergone the design modification) in comparison against previously cleared TC-100 Blade Plates described above. The specific type of pre-clinical testing conducted is described as:

- *Construct fatigue testing* of bone plate (and screw) constructs

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

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7135 Goodlet Farms Parkway
Cordova, Tennessee 38016

NOV 14 2011

Re: K112406
Trade/Device Name: PERI-LOC™ Periarticular Locked Plating System – Proximal Femur Locking Bone Plates
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: August 19, 2011
Received: August 22, 2011

Dear Mr. Henly:

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.

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,

for 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): K112406 (pg 1/1)

Device Name: PERI-LOC™ Periarticular Locked Plating System –
Proximal Femur Locking Bone Plates

Indications for Use:

PERI-LOC™ Periarticular Locked Plating System Proximal Femur Bone Plates, Bone Screws 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 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 - Proximal Femur Locking Bone Plates are for single use only.

Prescription Use X OR Over-the-Counter Use _____
(Per 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)

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

510(k) Number K112406