510(k) Summary of Safety and Effectiveness
PERI-LOC™ Bone Plating and Screw System

Submitted By:

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

JAN - 7 2009

Date: October 9, 2008

Contact Person:

David Henley, Regulatory Affairs Project Manager
Tel: (901) 399-6487 Fax: (901) 398-5146

Proprietary Name: PERI-LOC™ Bone Plating and Screw System
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
21 CFR 888.3040, smooth or threaded metallic bone fixation fastener – Class II

Device Product Code and Panel Code: HRS, HWC, KTT, LXT / Orthopedics / 87

Device Description:
The *PERI-LOC*™ Bone Plating and Screw System represents titanium versions of stainless steel *PERI-LOC*™ Periarticular Locked Plating System bone plates and bone screws previously cleared under K082516, K061352, K051735, and K033669. Like the predicate devices, the *PERI-LOC*™ Bone Plating and Screw System devices feature various lengths of straight and contoured locking bone plates; locking and non-locking bone screws, washers, plus a screw adapter accessory. Bone plates in the *PERI-LOC*™ Bone Plating and Screw System feature a screw-to-plate locking feature, which forms a locked, fixed-angle construct to aid in maintaining fracture reduction.

Intended Use:
The *PERI-LOC*™ Bone Plating and Screw System 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.

Technological Characteristics:
The *PERI-LOC*™ Bone Plating and Screw System is similar to legally-marketed devices listed below in that they share similar indications for use 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 and overall indications for use.

- PERI-LOC™ Periarticular Locked Plating System – Hexalobular Bone Screws (K082516)
- PERI-LOC™ Periarticular Locked Plating System – Proximal Femur (K072818)
- *PERI-LOC*™ Periarticular Locked Plating System – Locking Bone Plates & Screws for the Upper Extremity (K061352)
- *PERI-LOC*™ Locking Bone Plates and Locking Bone Screws for the Upper Extremity (K051735)
- Smith & Nephew Locking Bone Plate System (K033669)
- Smith & Nephew Bone Plate System (K993106)
- Synthes Large Fragment DCL System (K000682)
- Synthes Small Fragment DCL System (K000684)
- Synthes LCP Proximal Humerus Plate (K011815)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Smith & Nephew, Inc.
% Mr. David Henley
Orthopaedic Division
1450 Brooks Road
Memphis, TN 38116

JAN - 7 2009

Re: K083032
Trade/Device Name: PERI-LOC™ Bone Plating and Screw System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: October 9, 2008
Received: October 10, 2008

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 Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

K083032

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K083032

Device Name: PERI-LOC™ Bone Plating and Screw System

Indications for Use:

The **PERI-LOC™ Bone Plating and Screw System** 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.

Components in the **PERI-LOC™ Bone Plating and Screw 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)

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

510(k) Number K083032