K051735

510(k) Summary of Safety and Effectiveness

PERI-LOC® Locking Bone Plates and Locking Bone Screws for the Upper Extremity

JUL 19 2005

Submitted By:	Smith & Nephew, Inc., Orthopaedic Division 1450 Brooks Road Memphis, TN 38116
Date:	June 27, 2005
Contact Person:	David Henley, Senior Regulatory Affairs Specialist Tel: (901) 399-6487 Fax: (901) 398-5146
Proprietary Name:	**PERI-LOC® Locking Bone Plates and Locking Bone Screws for the Upper Extremity**
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:

PERI-LOC® Locking Bone Plates and Locking Bone Screws for the Upper Extremity are line additions to the PERI-LOC® Periarticular Locked Plating System cleared under K033669. Like the predicate devices listed below, the subject components include various sizes of contoured and straight, locking bone plates and 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 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:

Components comprising **PERI-LOC® Locking Bone Plates and Locking Bone Screws for the Upper Extremity** 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 – K033669
- Synthes LCP Proximal Humerus Plates – K041860
- Synthes 3.5mm LCP Distal Humerus System – K033995
- Synthes Small Fragment DCL System – K000684
- Howmedica Osteonics Numelock II Polyaxial Locking System – K041709
- Acumed, Inc. Congruent Bone Plate System – K012655
- Hand Innovations, Inc. Distal Volar Radius Anatomical Plate System – K050932

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 19 2005

Mr. David Henley
Senior Regulatory Affairs Specialist
Smith & Nephew, Inc.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K051735
Trade/Device Name: PERI-LOC® Periarticular Locked Plating System
Regulation Number: 21 CFR 888.3030, 888.3040
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories, Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HRS, HWC, KTT, LXT
Dated: June 27, 2005
Received: July 6, 2005

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 its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting 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): K051735

Device Name: PERI-LOC° Periarticular Locked Plating System

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° 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° Periarticular Locked Plating System are for single use only.

Prescription Use ___X___ (Per 21 CFR 801.109) OR Over-the-Counter Use ________ (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 K051735