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

Re: K110670
   Trade/Device Name: VLP FOOT Plating System and PERI-LOC Ankle Fusion
   Plating System – Locking Bone Plates and Screws
   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: June 30, 2011
   Received: July 1, 2011

Dear Mr. Henley:

This letter corrects our substantially equivalent letter of July 12, 2011.

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 (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 (301) 796-7100 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): K110670

Device Name: VLP FOOT Plating System and PERI-LOC Ankle Fusion Plating System - Locking Bone Plates and Screws

Indications for Use:

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP FOOT Plating System is indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

The Smith & Nephew PERI-LOC Ankle Fusion Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The PERI-LOC Ankle Fusion Plating System is indicated for ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus.

VLP FOOT Plating System and PERI-LOC Ankle Fusion Plating System bone plates and bone screws are for single use only.

Prescription Use X AND/OR Over-the-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]
(Division Sign-Out)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110670
Smith & Nephew
% Mr. David Henley
Regulatory Affairs Project Manager
1450 Brooks Road
Memphis, TN 38116

Re: K120667
Trade/Device Name: PERI-LOC Ankle Fusion Bone Plates, VLP 2.7mm
Extra Large Percutaneous Calcaneus Plate and Device Specific Instrument
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: March 2, 2012
Received: March 5, 2012

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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" (21 CFR 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

[Signature]

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): K120667

Device Name: PERI-LOC Ankle Fusion Plates and VLP Extra Large Percutaneous Calcaneus Plate

Indications for Use:

The Smith & Nephew PERI-LOC Ankle Fusion Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The PERI-LOC Ankle Fusion Plating System is indicated for ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus.

The Smith & Nephew VLP FOOT Plating System can be used in adolescent (12-18 years) and transitional adolescent (18-21 years) subpopulations and adults, as well as patients with osteopenic bone. The VLP FOOT Plating System is indicated for fracture fixation, reconstruction or arthrodesis of small bones, including those in the forefoot, midfoot and hindfoot.

PERI-LOC Ankle Fusion Bone Plates and the VLP Extra Large Percutaneous Calcaneus Plate 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 K120667