510(k) Summary of Safety and Effectiveness

SEP 14 2012

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM:
Ortho Solutions Limited
West Station Business Park
Spital Road
Maldon
ESSEX, CM9 6FF
United Kingdom

510(k) FIRM CONTACT:
Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
Tel. No. 952-492-5858
e-mail: allippincott@msn.com

DATE: May 20, 2012

TRADE NAME: Oxford Ankle Fusion Nail (AFN) System.

COMMON NAME: Intramedullary Nail

CLASSIFICATION: Intramedullary fixation rod (*see 21CFR, Sec. 888.3020)*

Single/Multiple component metallic bone fixation appliances and accessories (*see 21CFR, Sec. 888.3030)*.

DEVICE PRODUCT CODE: **HSB**

SUBSTANTIALLY EQUIVALENT DEVICES
DePuyACE – VersaNail™ TTC Fusion Nail (**K023115 & K003797**)
Smith & Nephew – TRIGEN™ Hindfoot Fusion Nail (**K043052**)
Stryker – T2®™ Ankle Arthrodesis Nail (**K051590, K020384**)
Biomet – Phoenix™ Nail System (**K091976, K081243**)
Wright Medical – VALOR®™ Ankle Fusion Nail (**K110552 & K090857**)
Integra – PANTA® Arthrodesis Nail (**K091788, K050882**)

DEVICE DESCRIPTION:
The Ortho Solutions Oxford Ankle Fusion Nail (AFN) System is composed of three(3) diameter (10, 11 & 12mm) sizes by two(2) lengths (150 & 180mm) as a straight nail, cannulated, to accept a 3.9mm Guide Pin. The cannulated nail is inserted through a dorsal heel incision over a guide wire using x-ray fluoroscopy within the ankle boney anatomy and distal tibia medullary canal. The guidewire is used to achieve adequate positioning. A Revision Nail in all sizes is also offered where the angled transverse hole is removed.

DEVICE DESCRIPTION CONTINUED:

A low-profile head 5.0mm Cortical Transverse Bone Screw (in 26 lengths of 20 - 115mm in 2 & 5mm increments) is used for proximal and distal multiple 'cross-screw' fixation after compression of the ankle joint space. Dynamization Slots(2) are located at the Proximal End of the nail. Also offered is a Standard and Locking End Cap - for closing the distal end of the nail. The Locking End Cap rests and locks against the most distal Transverse 5.0mm Cortical Screw. For completion of long bone fractures, End Caps in 3 lengths (+0, +5 & +10) and in 3 diameters (10, 11 & 12mm) are used for distal IM Nail Length Extension as necessary. As well, all End Caps seal the end of the nail to avoid ingrowth of tissues. All bone hole preparation and bone screw insertion is with the assistance of intra-operative x-ray fluoroscopy. All implant components are offered '*Sterile*' for *Single Use*.

With the Intramedullary Nail inserted into the ankle bone, an instrument 'Targeting Arm' with alignment holes is attached to the distal end of the nail. This external Targeting Arm allows proper orientation, preparation, and alignment of the proper cannula for transverse and angled drilling of bone screw holes into the nail and ankle anatomy cortical and cancellous bone. The bone hole preparation is for proper alignment to the referenced transverse and angled holes within the Intramedullary Nail for insertion of Transverse 5.0mm Cortical Bone Screws.

All implant components are made from 6-4 Alloyed Titanium material to ASTM F 136 and are anodized with a Type II surface perparation.

The IM Nail, End Cap and Transverse Screws may be removed when long bone fracture(s) are healed or the ankle joint space is fused.

A full complement of instrumentation (external Targeting Arm Main Jig, guide wire/pins, drill guides/sleeves, cannulated tissue protector sleeves, depth gauge, reamers, reaming rod, drills, drivers, cannulated guide tube & trocar, etc.) is available with the system. A *'sterile - single use'* disposable pack is available encompassing a guide pin, guide rod, drills, reamer, reaming rod and exchange tube. A implant extraction/removal instrumentation set is also made available.

INTENDED USE:

The Ortho Solutions Limited **Oxford Ankle Fusion Nail (AFN) System** is a tibiotalocalcaneal (TTC) solid fusion system that has been developed for the following indications:

- **Failed ankle replacement**
- **Arthritis of ankle and subtalar joint**
- **Correcting neuromuscular imbalance of hindfoot, where bone fusion is required**
- **Revision of failed ankle and/or subtalar fusion**
- **Revision of failed Tibiotalocalcaneal (TTC) fusion**
- **Talar Avascular Necrosis (AVN)**
- **Charcot**
- **Trauma**
- **Neuroarthropathy**
- **Pseudoarthrosis**
- **Rheumatoid arthritis**

EQUIVALENCE:

The Ortho Solutions Limited Oxford Ankle Fusion Nail (AFN) System is substantially equivalent(SE) to predicate systems from many orthopedic companies (as listed).

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Ortho Solutions Limited Oxford Ankle Fusion Nail (AFN) System is Similar in Material, Geometry Design/Markings, and Indications to many predicate systems currently sold in the U.S. market.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The Ortho Solutions Limited Oxford Ankle Fusion Nail (AFN) System is shown to be safe and effective for use as '**sterile**' and for **single-use** in a surgical setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 14 2012

Ortho Solutions Limited
% Engineering Consulting Services
% Mr. Al Lippincott
3150 E. 200th St.
Prior Lake, Minnesota 55372

Re: K121575
Trade/Device Name: Oxford Ankle Fusion Nail (AFN) System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: July 31, 2012
Received: August 17, 2012

Dear Mr. Lippincott:

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" (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,

for Mark N. Melkerson

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

Enclosure

Indications for Use

510(k) NUMBER: **K121575**

DEVICE NAME: **Oxford Ankle Fusion Nail (AFN) System**

The Ortho Solutions Limited **Oxford Ankle Fusion Nail (AFN) System** is a tibiotalocalcaneal (TTC) solid fusion system that has been developed for the following indications:

- **Failed ankle replacement**
- **Arthritis of ankle and subtalar joint**
- **Correcting neuromuscular imbalance of hindfoot, where bone fusion is required**
- **Revision of failed ankle and/or subtalar fusion**
- **Revision of failed Tibiotalocalcaneal (TTC) fusion**
- **Talar Avascular Necrosis (AFN)**
- **Charcot**
- **Trauma**
- **Neuroarthropathy**
- **Pseudoarthrosis**
- **Rheumatoid arthritis**

Prescription Use **XXXX** AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(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 K121575