510(k) Summary of Safety and Effectiveness

JUL 2 3 2014

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
www.orthosolutions.com

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: June 20, 2014

TRADE NAME: Ortho Solutions – UltOS Plating System

COMMON NAME: Foot Bone Plate System

CLASSIFICATION: Smooth or threaded metallic bone fixation fastener (*per 21CFR888.3040*) – Screw, Fixation, Bone

Single/multiple component metallic bone fixation appliance and accessories (*per 21CFR888.3030*) – Plate, Fixation, Bone

DEVICE PRODUCT CODE: **HRS**

SUBSEQUENT PRODUCT CODE: **HWC, KTT**

SUBSTANTIALLY EQUIVALENT DEVICES
Ortho Solutions - FPS System (**K111678**)
Wright Medical- DARCO MFS & MRS Systems (**K061808**, **K100359**)
Synthes - Variable Angle LCP Forefoot/Midfoot System (**K100776**)

DEVICE DESCRIPTION: The ***Ortho Solutions UltOS Plating System*** is designed to address a variety of indications in rearfoot, midfoot, and forefoot reconstuctive fixation surgery. The overall system is composed of ***Twelve(12) Plate Types*** that accept both a smaller 2.7mm and larger 3.5mm Locking/ Non-locking Screw (in various lengths of 8mm thru 50mm) – with all screw heads of uniform size to fit any plate type. The UltOS System *'Twelve(12) Plate Types'* consist of the following:

Ortho Solutions, Limited - 510(k) Summary:

DEVICE DESCRIPTION CONTINUED:

1). A Arthrodesis Wedge Plate (**AWP**) in 5 sizes of 0, 2, 4, 6 & 8mm plate wedge widths,
2). A General Fusion Straight Plate (**GFS**) in 2 sizes of a 2 & 4 screw hole plate,
3). A General Fusion "T" Plate (**GFT**) in 3 sizes of a 2, 4 & 6 screw hole plate,
4). A Metatarsophalangeal Plate (**MTP**) in 3 sizes, Left & Right, of a Small, Medium & Large plate size,
5). A Opening Wedge Locking Plate (**OWL**) in 6 sizes of 0, 3, 4, 5, 6 & 7mm plate wedge widths,
6). A Opening Wedge Plate (**OWP**) in 6 sizes of a 0, 2.5, 3, 4, 5 & 7mm plate wedge widths,
7). A Calcaneal Step Plate (**CSP**) in 3 sizes of 8, 10 & 12mm plate step heights,
8). A General Fusion "X" Plate (**GFX**) in 4 sizes of a Extra Small, Small, Medium & Large plate size,
9). A Lapidus Plate (**LAP**) in 4 sizes, Left & Right, of a 0, 2, 4 & 6mm plate offset heights,
10). A Rearfoot Reconstruction Plate (**RRP**) in 3 sizes of a 6, 8 &14 screw hole plate,
11). A Tarsal Fusion Plate (**TFP**) in 3 sizes of a 12, 14 & 16mm plate length, and
12). A Universal Locking Plate (**ULP**) in 5 sizes of a 12, 16, 20, 24 & 30mm plate length.

Screw diameters of 2.7mm and 3.5mm with either Locking or Non-Locking features and Cannulated 3.5mm self tapping screws in various lengths are also included in the UltOS Plating System.

Associated instrumentation such as compression and distraction pliers, disposable drills & wires/guide wires, drill guides, T8 torx screw-drivers and ancillary instrumentation is available. All plates and screws are manufactured from Alloyed Titanium Ti-6Al-4V to ASTM F136. All plates, screws, drills and K-wires are offered both **'Sterile'** and **'Non-Sterile'** to the customer.

INTENDED USE:

The ***intended use*** of the *Ortho Solutions UltOS Plating System* fixation device(s) is to draw two or more aligned small bone fragments together to facilitate healing.

The *Ortho Solutions UltOS Plating System* is **indicated for use** in stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones in the feet, ankles, and toes skeleton.

This implant should only be used with the Ortho Solutions UltOS Plating System. Combination with other implants or instrumentation is not permissible.

The Ortho Solutions UltOS Plating System is not intended for spinal use.

EQUIVALENCE:	The *Ortho Solutions UltOS Plating System* is substantially equivalent to predicate systems from many orthopedic companies (as listed). No nonclinical testing was used in the determination of substantial equivalence.
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS	The *Ortho Solutions UltOS Plating 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 UltOS Plating System* is shown to be safe and effective as **'sterile'** and **'non-sterile'** for single-use in a surgical setting.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 23, 2014

Ortho Solutions, Limited
% Mr. Al Lippincott
Engineering Consulting Services, Inc.
U.S. Agent and Official Correspondent to Ortho Solutions, Limited
3150 E. 200th St.
Prior Lake, Minnesota 55372

Re: K141784
Trade/Device Name: Ortho Solutions UltOS Plating System
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, KTT
Dated: June 20, 2014
Received: July 2, 2014

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins

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

Enclosure

Indications for Use

510(k) NUMBER: K141784

DEVICE NAME: **Ortho Solutions UltOS Plating System**

INDICATIONS FOR USE:

The ***intended use*** of the *Ortho Solutions UltOS Plating System* fixation device(s) is to draw two or more aligned small bone fragments together to facilitate healing.

The *Ortho Solutions UltOS Plating System* is **indicated for use** in stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of small bones in the feet, ankles, and toes skeleton.

This implant should only be used with the Ortho Solutions UltOS Plating System. Combination with other implants or instrumentation is not permissible.

The Ortho Solutions UltOS Plating System is not intended for spinal use.

Prescription Use __XX__ 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)

Elizabeth L. Frank -S

Division of Orthopedic Devices