



November 20, 2020

Ortho Solutions UK Ltd
Andy Leither
US Technical and Development Director
West Station Business Park
Spital Road
Essex, CM9 6FF
United Kingdom

Re: K202764

Trade/Device Name: Ortho Solutions 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, HTN

Dated: September 16, 2020

Received: September 21, 2020

Dear Andy Leither:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K202764

Device Name

Ortho Solutions Plating System

Indications for Use (Describe)

The Ortho Solutions Plating System is indicated for use in stabilization and fixation of fractures or osteotomies, revision procedures, joint fusion, and reconstruction of small bones of the feet and ankles, including the toes, talus, and calcaneus; the distal fibula and tibia; as well as the fingers, hands, and wrists.

In addition, the non-locking screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K202764
510(k) SUMMARY

Submitter Information

Submitters Name: Ortho Solutions UK Ltd
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United Kingdom

Telephone Number: +44 1621 843 599
Fax Number: +44 1621 858 953
Prepared By: Andy Leither
Contact Person: Andy Leither
Date Prepared: 09/16/2020

Device Information

Trade Name: Ortho Solutions Plating System

Common Name: Plate, Fixation, Bone
Screw, Fixation, Bone
Washer, Bolt Nut

Device Classification: Class II per 21 CFR 888.3030 (Primary)
Single/multiple component metallic bone fixation appliances and accessories.
Panel: Orthopedic

Class II per 21 CFR 888.3040
Smooth or threaded metallic bone fixation fastener.
Panel: Orthopedic

Class II per 21 CFR 888.3030
Single/multiple component metallic bone fixation appliances and accessories.
Panel: Orthopedic

Product Code: HRS (Primary)
HWC
HTN

Material Composition: Titanium Alloy (Ti-6AL-4V ELI) per ASTM F136

Device Description:	The Ortho Solutions Plating System is a set of implantable metallic (Titanium Alloy) bone plates, locking and non-locking screws of various lengths. The system consists of a series of tubular plates of varying lengths as well as anatomically contoured plates. Locking and non-locking screws are provided in Ø2.7mm, Ø3.5mm, & Ø4.0mm in various lengths and are compatible with all plates. All implants are made from Titanium Alloy (Ti-6AL-4V ELI) per ASTM F136 and are provided non-sterile.
Primary Predicate Device:	Ortho Solutions Trauma Plates for Osteosynthesis, K120360
Additional Predicate Devices:	Ortho Solutions UltOS Plating System, K141784 Wright Medical ORTHOLOC 3Di Ankle Fracture Plating System, K163044
Indications for Use:	<p>The Ortho Solutions Plating System is indicated for use in stabilization and fixation of fractures or osteotomies, revision procedures, joint fusion, and reconstruction of small bones of the feet and ankles, including the toes, talus, and calcaneus; the distal fibula and tibia; as well as the fingers, hands, and wrists.</p> <p>In addition, the non-locking screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.</p>
Technological Characteristics:	The Ortho Solutions Plating System is substantially equivalent in material, geometry, design, and indications to the predicate devices.
Performance Analysis:	Performance testing per ASTM F382, engineering analysis and rationale was completed for the plates to demonstrate substantial equivalence for static and fatigue bending strength. Performance testing was completed for the screws per ASTM F543 to demonstrate substantial equivalence with respect to torsional strength, insertion torque, and pullout strength.
Conclusion:	The Ortho Solutions Plating System has been compared to the previously cleared predicate devices with respect to indications for use, materials, mechanical performance, and technological characteristics. The design characteristics of the subject device do not raise new types of questions regarding safety or efficacy. These comparisons demonstrate that the Ortho Solutions Plating System is substantially equivalent to the predicate devices.