April 13, 2021

Ortho Solutions UK Ltd
Andy Leither
US Technical and Development Director
West Station Business Park, Spital Road
Maldon, CMF 6FF GBR

Re: K210658
Trade/Device Name: Volition 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: March 4, 2021
Received: March 4, 2021

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 -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210658

Device Name
Volition Plating System

Indications for Use *(Describe)*

The Volition 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.

K210658 - 510(k) SUMMARY

Submitter Information

Submitters Name:	Ortho Solutions UK Ltd
Address:	West Station Business Park Spital Road Essex, CM9 6FF 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:	Volition 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 Volition Plating System is a set of implantable metallic (Titanium Alloy) bone plates consisting of a series of tubular plates of varying lengths as well as anatomically contoured plates. The Volition Plating System plates are provided with locking and non-locking in Ø2.7mm, Ø3.5mm, & Ø4.0mm previously cleared under K202764. All implants are made from Titanium Alloy (Ti-6AL-4V ELI) per ASTM F136 and are provided non-sterile.
Primary Predicate Device:	Ortho Solutions Plating System, K202764
Additional Predicate Devices:	Ortho Solutions Trauma Plates for Osteosynthesis, K120360
Indications for Use:	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.
Technological Characteristics:	The Volition Plating System is substantially equivalent in material, geometry, design, and indications to the predicate devices.
Performance Analysis:	Engineering analysis of the subject device was employed to demonstrate the Volition System bone plates are substantially equivalent to the predicate(s) with respect to bending strength performance.
Conclusion:	The Volition 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 Volition Plating System is substantially equivalence to the predicate devices.