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

Re: K163489
Trade/Device Name: OrthoSolutions 'System 26' Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: November 30, 2016
Received: December 12, 2016

March 8, 2017

Dear Mr. Al 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

Sincerely,

Mark N. Melkerson -S

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

Enclosure
Indications for Use

OrthoSolutions 'System26' Bone Screws

The OrthoSolutions ‘System26’ cannulated screws (headed and headless compression) and washers are indicated for use over a guide pin or wire for aligned bone fracture repair and arthrodesis, osteotomy, joint fusion and bone fragment fixation appropriate with the size of the screw. Washers of matching size to the headed cannulated bone screw may be used in certain applications for deficient osteopenic bone. The non-cannulated 2.0 (headed, headless compression and Twist-Off) bone screws are applicable, as well, for bone fracture repair and arthrodesis, osteotomy, joint fusion and bone fragment fixation appropriate with the size of the screw.

‘System26’ non-cannulated 2.0mm (headed, headless compression and Twist-Off) bone screws and cannulated (headed and headless compression) bone screw sizes of 2.0mm, 2.5mm 3.0mm are indicated for treating small bone fractures as well as performing osteotomies, arthrodesis and joining cancellous bone fragments in the upper and lower limb and extremities.

‘System26’ cannulated bone screw sizes (headless compression and headed with optional matching washer) of 4.0mm, 5.0mm, 6.5mm, and 8.0mm are indicated to be used with large and long bones. Specific indications, which are dependent in part on the diameter of the screw include: Minimally invasive bone fracture/joint reconstructions; Additive osteosynthesis for complex joint fractures; Multiple-fragment joint fractures; Femoral neck and femoral head fractures; Femoral supracondylar fractures; Tibial plateau fractures; Fractures of the head of the humerus; Fractures of the tibia; Cooper fractures of the tibia; Bone fractures of the radius, wrist, ankle, elbow, and shoulder; Ligament fixation of the proximal humerus; Bone fractures of the acetabulum and dorsal pelvic ring; Condylar fractures; Ligament avulsion injuries; Malleolar and navicular fractures; Bone fractures of the calcaneus and talus; Arthrodesis of the ankle joint; Arthrodesis of foot joints and; Avulsion fractures.

The OrthoSolutions 'System26' Bone Screws are not intended for spinal use.

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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510(k) Summary of Safety and Effectiveness

In Accordance with 21 CFR 807.92 of the Federal Code of Regulations
510(k) Summary

NAME OF FIRM: OrthoSolutions UK Limited
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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: February 24, 2017

TRADE NAME: OrthoSolutions ‘System26’ Bone Screws

COMMON NAME: Headed and Headless Compression Cannulated Bone Screw & Washer System

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

Single/multiple component metallic bone fixation appliance and accessories (per 21CFR888.3030) Class II – Washer, Bolt, Nut, Non-Spinal, Metallic

DEVICE PRODUCT CODE: HWC

SUBSEQUENT PRODUCT CODE: HTN

SUBSTANTIALLY EQUIVALENT DEVICES

OrthoSolutions - Cannulated Bone Screws & Washers (K110895)
OrthoSolutions – TwistFix & Compression Screws (K111678)
Vilex - Cannulated Bone Screws (K991197, K014154)
Ascent Medical – Cannulated Bone Screws & Washers (K150693)
I.T.S. GmbH – HCS Compression Screw (K131722)
DEVICE DESCRIPTION: OrthoSolutions ‘System26’ Bone Screws are comprised of non-cannulated/cannulated bone screws and washers manufactured from Titanium Alloy (to ISO 5832-3/ASTM F136) for implantation within the human body. The instrumentation is made from medical grades of stainless steel and silicon. The ‘System26’ implants are threaded screws offered in both a ‘headed’ and ‘headless compression’ design. The implant screws are available in a range of diameter sizes between 2mm thru 8mm, (each identified with a Type III color anodising) with lengths between 10mm (shortest length) and 120mm (longest length). The implant screw devices (headed with washers and headless compression) and associated instrumentation are available in specifically designed, modular trays and are provided ‘Non-sterile’ to the end user for ‘Single Use’. The ‘System26’ instruments include guide wires and size specific guides, drill bits and size specific guides, tissue protectors, depth gauges, countersinks, screw driver shafts, ratcheting screw driver handles and bone distractors. These instruments are used to ensure correct positioning and placement of the screws.

INTENDED USE: The OrthoSolutions ‘System26’ cannulated screws (headed & headless compression) and washers are indicated for use over a guide pin or wire for aligned bone fracture repair and arthrodesis, osteotomy, joint fusion and bone fragment fixation appropriate with the size of the screw. Washers of matching size to the headed cannulated bone screw may be used in certain applications for deficient osteopenic bone. The non-cannulated 2.0 (headed, headless compression and Twist-Off) bone screws are applicable, as well, for bone fracture repair and arthrodesis, osteotomy, joint fusion and bone fragment fixation appropriate with the size of the screw.

‘System26’ non-cannulated 2.0mm (headed, headless compression and Twist-Off) bone screws and cannulated (headed and headless compression) bone screw sizes of 2.0mm, 2.5mm 3.0mm are indicated for treating small bone fractures as well as performing osteotomies, arthrodesis and joining cancellous bone fragments in the upper and lower limb and extremities.

‘System26’ cannulated bone screw sizes (headless compression and headed with optional matching washer) of 4.0mm, 5.0mm, 6.5mm, and 8.0mm are indicated to be used with large and long bones. Specific indications, which are dependent in part on the diameter of the screw include: Minimally invasive bone fracture/joint reconstructions; Additive osteosynthesis for complex joint fractures; Multiple-fragment joint fractures; Femoral neck and femoral head fractures; Femoral supracondylar fractures; Tibial plateau fractures; Fractures of the head of the humerus; Fractures of the tibia; Cooper fractures of the tibia; Bone fractures of the radius, wrist, ankle, elbow, and shoulder; Ligament fixation of the proximal humerus; Bone fractures of the acetabulum and dorsal pelvic ring; Condylar fractures; Ligament avulsion injuries; Malleolar and navicular fractures; Bone fractures of the calcaneus and talus; Arthrodesis of the ankle joint; Arthrodesis of foot joints and; Avulsion fractures.
OrthoSolutions UK Limited - K163489 - 510(k) Summary:

The OrthoSolutions ‘System26’ Bone Screws are not intended for spinal use.

EQUIVALENCE: The OrthoSolutions ‘System26’ Bone Screws is substantially equivalent to predicate systems. An Engineering Analysis was provided to demonstrate Substantial Equivalence (SE).

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS: The OrthoSolutions ‘System26’ Bone Screws is similar in Material, Geometry, Design, and Indications to predicate systems legally marketed in the US.

CONCLUSIONS: Based on the similarity in Material, Geometry, Design, and Indications for Use, as well as an Engineering Analysis, the OrthoSolutions ‘System26’ Bone Screws has been demonstrated to be substantially equivalent to the predicate devices.