July 26, 2019

ActivOrtho, Inc.
% Lisa Pritchard
Regulatory, Quality & Compliance Consultant
DuVal & Associates, P.A.
825 Nicollet Mall, Suite 1820
Minneapolis, Minnesota 55402

Re: K191817
Trade/Device Name: ActivOrtho Continuous Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 3, 2019
Received: July 5, 2019

Dear Lisa Pritchard:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191817

Device Name

ActivOrtho Continuous Compression Screw System

Indications for Use *(Describe)*

The ActivOrtho Continuous Compression Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of small bones and small bone fragments.

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

1. SUBMITTER

ActivOrtho, Inc.
14405 21st Ave N, Suite 120
Plymouth, MN 55447
Phone: 651.341.3805
Contact Person: Paul Hindrichs
Date Prepared: July 26, 2019

2. DEVICE

Name of Device: ActivOrtho Continuous Compression Screw System
Common or Usual Name: Bone Screw
Classification Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC

3. PREDICATE DEVICE

Primary Predicate: ActivOrtho Nitinol Compression Screw System, K181610
Additional Predicate 1: dynaMX™ Nitinol Compression Screw, K160427
Additional Predicate 2: Synthes 4.0 Cannulated Screw, K963192
These predicates have not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The ActivOrtho Continuous Compression Screw System is a cannulated Nitinol bone screw having various sizes to accommodate a variety of applications. The screws are headed, cannulated, and partially threaded. The continuous compression screw incorporates a helical expansion section in the smooth shaft of the screw which elongates as the distal thread engages bone to produce a continuous compression force across the fracture site.

5. INDICATIONS FOR USE

The ActivOrtho Continuous Compression Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of small bones and small bone fragments.

6. MATERIALS

The ActivOrtho Continuous Compression Screw implants are made from Nitinol (ASTM F2063)

7. PRIMARY PREDICATE DEVICE

ActivOrtho Nitinol Compression Screw (ActivOrtho, Inc. - K181610)

8. ADDITIONAL PREDICATE DEVICES

dynaMX Nitinol Compression Screw (MX Orthopedics Corporation – K160427)

Synthes 4.0 Cannulated Screw (Synthes USA – K963192)

9. NON-CLINICAL PERFORMANCE DATA

Torsional properties, driving torque and axial pullout strength testing was performed on a worst-case device according to ASTM F543. Corrosion susceptibility testing was performed according to ASTM F2129. In addition, construct static and dynamic bend testing, and compression force testing were performed.

10. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The ActivOrtho Continuous Compression Screw System possesses the same technological characteristics as one or more of the predicate devices. These include performance, basic design, material, method of stabilization and sizes (dimensions are comparable to those offered by the predicate systems). The ActivOrtho Continuous Compression Screw and the primary predicate device are manufactured from the same material, are cannulated, have the same lengths, and same screw thread geometry.

The ActivOrtho Continuous Compression Screw includes a helical expansion section in the smooth shaft of the screw that is not present on the predicate devices. While the ActivOrtho Continuous Compression Screw System is not identical to the predicate devices, the differences were shown not to raise new questions of safety and effectiveness. Therefore, the fundamental scientific technology of the ActivOrtho Continuous Compression Screw System is similar to previously cleared devices.

11. CONCLUSION

The ActivOrtho Continuous Compression Screw System possesses the same intended use and has technological characteristic similar to the predicate devices. Therefore, the ActivOrtho Continuous Compression Screw System is substantially equivalent to the predicates.