March 12, 2019

ActivOrtho, Inc.
℅ Karen Warden
Representative/Consultant
BackRoads Consulting, Inc.
PO Box 566
Chesterland, Ohio 44026-0566

Re: K181610
Trade/Device Name: ActivOrtho Nitinol 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: January 29, 2019
Received: January 31, 2019

Dear Karen Warden:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K181610

Device Name
ActivOrtho Nitinol Compression Screw System

Indications for Use *(Describe)*

The ActivOrtho Nitinol 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date:	8 March 2019
Sponsor:	ActivOrtho, Inc. 12820 34th Ave N Plymouth, MN 55441 Phone: 651-341-3805
Sponsor Contact:	Paul Hindrichs
510(k) Contact:	Karen E. Warden, PhD BackRoads Consulting, Inc. PO Box 566 Chesterland, OH 44026 Office: 440.729.8457
Trade Names:	ActivOrtho Nitinol Compression Screw System
Common Name:	Bone screw
Regulatory Class:	Class II
Classification Name / Regulation / Product Code:	Smooth or threaded metallic bone fixation fastener / 888.3040 / HWC
Device Description:	The ActivOrtho Nitinol Compression Screw System includes cannulated, partially threaded bone screws having a 4mm diameter in a variety of lengths to accommodate various applications.
Indications for Use:	The ActivOrtho Nitinol 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.
Materials:	The ActivOrtho Nitinol Compression Screw implants are made from Nitinol (ASTM F2063).
Primary Predicate:	dynaMX™ Nitinol Compression Screw (MX Orthopedics Corporation -- K160427)
Additional Predicates:	Synthes 4.0 Cannulated Screw (Synthes USA – K963192); Vilex Cannulated Bone Screw (Vilex Inc. – K973309), Zimmer Cannulated Screw System (Pioneer Surgical Technology – K102903)
Performance Data:	Torsional properties, driving torque and axial pullout strength testing was performed on a worst case device according to ASTM F543. In addition, corrosion susceptibility testing was performed per ASTM F2129.
Technological Characteristics:	The ActivOrtho Nitinol 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). While the ActivOrtho Nitinol 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 Nitinol Compression Screw System is similar to previously cleared devices.
Conclusion:	The ActivOrtho Nitinol Compression Screw System possesses indications for use the same as and technological characteristics similar to the predicate devices. Therefore the ActivOrtho Nitinol Compression Screw System is substantially equivalent to the predicates.