June 26, 2023

University of Utah, Department of Orthopaedics
% Hollace Rhodes
Vice President
MCRA, LLC
803 7th Street NW, 3rd Floor
Washington, District of Columbia 20001

Re: K230867
Trade/Device Name: Bone Bolt System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: March 29, 2023
Received: March 29, 2023

Dear Hollace Rhodes:

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, M.P.H.
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)*
K230867

Device Name
Bone Bolt System

Indications for Use *(Describe)*
The 3.5mm, 4.0mm and 4.5mm Bone Bolt System is indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones, small bone fragments, long bones, and long bone fragments of clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneus, femur, and fibula, and the bones of the hand and foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by Bone Bolt fixation.

The 5.0mm, 6.0mm and 7.0mm Bone Bolt System is indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments of humerus, radius, ulna, tibia, femur and fibula, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by Bone Bolt fixation.

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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510(k) Summary

Device Trade Name:	Bone Bolt System
Sponsor:	University of Utah, Department of Orthopaedics 590 Wakara Way Salt Lake City, UT 84108
Contact:	T. Wade Fallin, M.S. Research Professor Phone: (801) 587-2938 Fax: (801) 587-5411
Prepared by:	MCRA, LLC
Date Prepared:	June 26, 2023
Common Names:	Screw, Fixation, Bone Washer, Bolt Nut
Classifications:	21 CFR 888.3040 21 CFR 888.3030
Class:	II
Product Codes:	HWC HTN

Indications for Use:
The 3.5mm, 4.0mm and 4.5mm Bone Bolt System is indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of small bones, small bone fragments, long bones, and long bone fragments of clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, calcaneus, femur, and fibula, and the bones of the hand and foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by Bone Bolt fixation.

The 5.0mm, 6.0mm and 7.0mm Bone Bolt System is indicated for fixation of fractures, fusions, osteotomies, non-unions, and malunions of long bones and long bone fragments of humerus, radius, ulna, tibia, femur and fibula, pelvis, sacrum, and the bones of the foot in adults and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by Bone Bolt fixation.

Device Description:
The Bone Bolt System consists of various sizes and lengths of bolts and nut-sleeves, which are implanted from opposing bone surfaces to provide stabilization of bones and bone fragments for the fixation of fractures, arthrodeses, and osteotomies. The bolts and nut-sleeves are cannulated for use with guidewires for precise placement in bone. The Bone Bolt System includes optional washers of various sizes.

Predicate Devices:
Primary Predicate
DePuy Synthes Cortex and Cannulated Screws (K161616)

Additional Predicate
Synthes 3.5mm Cortex Screws (K043185)

Reference Device
Acumed Frag-Loc® System (K130986)

Materials:
The Bone Bolt implants are made from Ti-6Al-4V per ASTM F136. The Bone Bolt accessories are made from stainless steel per ASTM F899, polypropylene and silicone.

Performance Data:
The Bone Bolt System performance was characterized through the following tests, in accordance with ASTM F543-17 and ASTM F1264-16 Annex A4:

- Torsional Strength Testing
- Driving Torque Testing
- Axial Pull-out Strength Testing
- Static and Dynamic Bending Testing

No clinical or animal testing was conducted.

Substantial Equivalence:
The Bone Bolt System has the same intended use and uses the same design, materials, principles of operations, and similar range of sizes as the predicate devices, the DePuy Synthes Cortex and Cannulated Screws (K161616), and Synthes 3.5mm Cortex Screws (K043185). Side-by-side performance testing demonstrates that the Bone Bolt System has equivalent or statistically significantly better performance than its predicates. The Bone Bolt System's similarities in technological characteristics to its predicates and the reference device, the Acumed Frag-Loc® System (K130986), further support its substantial equivalence. Thus, the Bone Bolt System is substantially equivalent to the DePuy Synthes Cortex and Cannulated Screws (K161616), Synthes 3.5mm Cortex Screws (K043185).