December 23, 2020

WishBone Medical, Inc.
Mary Wentorf
Executive VP, Product Development, QA/RA
100 Capital Drive
Warsaw, Indiana 46582

Re: K203467
Trade/Device Name: WishBone Medical Plate and Screw 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: November 23, 2020
Received: November 25, 2020

Dear Mary Wentorf:

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)*
K203467

Device Name

WishBone Bone Plate and Screw System

Indications for Use *(Describe)*

The WishBone Bone Plate and Screw System is used for pediatric and adult patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis.

Indications for use include fractures of the clavicle, scapula, humerus, ulna, radius, middle hand, metacarpals, pelvis acetabulum, femur, fibula, tibia, metatarsals and middle foot bones, and treatment of the calcaneus.

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

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the WishBone Bone Plate and Screw System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, "The Special 510(k) Program", issued on September 13, 2019.

1. SUBMITTER

Applicant	WishBone Medical, Inc.
Establishment Registration Number	3013680140
Contact	Mary Wentorf
Date Prepared	11/23/2020

2. SUBJECT DEVICE

Name of Device	WishBone Medical Plate and Screw System
Common Name	Bone Plates and Bone Screws
Classification Name	Screw, Fixation, Bone (21 CFR 888.3040) Washer, Bolt Nut (21 CFR 888.3030)
Product Code	HWC HTN
Regulatory Class	II
510(k) Review Panel	Orthopedic Devices (OHT6)

3. PREDICATE DEVICE(S)

Primary Predicate	K180736 - WishBone Bone Plate and Screw System
Reference Device(s)	K123890 – Acumed Cannulated Screw System

4. DEVICE DESCRIPTION

The purpose of this subject 510(k) is to introduce 4.0mm diameter cannulated screws and washers to the bone plate and screw system cleared under K180736.

5. INDICATIONS FOR USE

The WishBone Medical Plate and Screw System is used for pediatric and adult patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis.

Indications for use include fractures of the clavicle, scapula, humerus, ulna, radius, middle hand, metacarpals, pelvis acetabulum, femur, fibula, tibia, metatarsals and middle foot bones, and treatment of the calcaneus.

6. SUMMARY OF TECHNICAL CHARACTERISTICS

The rationale for substantial equivalence is based on consideration of the following characteristics:

a. **Intended Use**: Same as predicate

510(k) Summary

b. **Indications for Use**: Same as predicate
c. **Materials**: Same as predicate
d. **Design Features**: Similar to predicate
e. **Sterilization**: Same as predicate

7. SUMMARY OF PERFORMANCE DATA

a. **NON-CLINICAL**: Engineering analysis and mechanical testing was conducted in compliance with ASTM F543-17 *Standard Specification and Test Methods for Metallic Medical Bone Screws* and with performance standards defined within the FDA guidance document *Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway*. Evaluations conducted include:
   - Predicted Shear Failure - Confirmed pullout out strength met performance criteria defined with the FDA guidance document.
   - Torsional Strength – Compared torsional strength of the screw shafts to legally marketed predicate cannulated screws per ASTM F543-17.
   - Breaking Torque of 4.0mm Cannulated Screws at the Hexalobe Drive Feature – Confirmed the screw head meets the torsional yield strength as defined in the FDA guidance document.

b. **CLINICAL**: Clinical data was not deemed necessary for the subject device.

8. CONCLUSION

The subject device has the same intended use and indications for use as the WishBone Bone Plate and Screw System. The subject device has same/similar technological characteristics to the predicate, and the performance data and analyses demonstrates that:

- Any differences do not raise new questions of safety and effectiveness; and
- The proposed device is at least as safe and effective as the legally marketed predicate devices.