January 27, 2022

WishBone Medical, Inc.
Ramakrishna Bajaj
Regulatory Affairs Specialist
100 Capital Drive
Warsaw, Indiana 46582

Re: K213489
Trade/Device Name: Wishbone Medical Plate and Screw System: 3.0mm Screws and 7-Hole Straight Fibula Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 29, 2021
Received: November 1, 2021

Dear Ramakrishna Bajaj:

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,

For: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213489

Device Name
WishBone Medical Plate and Screw System: 3.0mm Screws and 7-Hole Straight Fibula Plate

Indications for Use *(Describe)*
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.

Specifically, the Straight Fibula Plates are intended for use in infant, child, and adolescent pediatric subgroups and adult patients.

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."

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the WishBone Medical Wishbone Plate and Screw: 3.0mm Screws and 7-Hole Straight Fibula Plate 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document *Format for Traditional and Abbreviated 510(k)s*, issued in September 2019.

SUBMITTER INFORMATION	
Applicant	WishBone Medical, Inc.
Address	100 Capital Drive Warsaw, IN 46582
Phone Number	(574)306-4006
Establishment Registration Number	3013680140
Name of Contact Person	Ramakrishna Bajaj
Date Prepared	October 29, 2021
NAME OF DEVICE	
Trade or Proprietary Name	WishBone Medical Plate and Screw System
Common or usual name	Plate, Fixation, Bone (Primary) Screw, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories (Primary) Smooth or threaded metallic bone fixation fastener.
Regulatory Classification	II
510(k) Review Panel	Orthopedic and Rehabilitation Devices
Regulation	21 CFR §888.3030 (Primary): Single/multiple component metallic bone fixation appliances and accessories. 21 CFR §888.3040: Smooth or threaded metallic bone fixation fastener; Class II
Product Code(s)	HRS(Primary), HWC
Primary Predicate Device	Wishbone Medical Plate and Screw System (K180736)
Device Description	The WishBone Medical 7-Hole Straight Fibula Plate and WishBone Medical 3.0mm Cortical Screws and Locking Screws are wrought titanium alloy plate and screws (per ASTM F136) that are being added to the existing WishBone Medical Plate and Screw System as a line extension.
Intended Use of the Device	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	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. Specifically, the Straight Fibula Plates are intended for use in infant, child, and adolescent pediatric subgroups and adult patients.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

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

a. Intended Use: The subject device and predicate systems have the same intended use. No new or increased risks are identified.
b. Indications for Use: The subject device and predicate systems have the same intended use. No new or increased risks are identified
c. Materials: The subject device is manufactured from the same materials. Therefore, no new or increased risks have been identified.
d. Design Features: The subject device design is similar to the predicates. No new or increased risks are identified.
e. Sterilization: The subject and predicate devices have the same sterilization method and dose. Therefore, no new or increased risks have been identified.

PERFORMANCE DATA

NON-CLINICAL TESTING

Engineering analyses were conducted on the WishBone Medical 7-hole Fibula Plate, and 3.0mm Cortical and Locking Screws to demonstrate substantial equivalence with the predicate device, addressing:

- Axial Pullout Strength per FDA Guidance "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway" issued December 11, 2020.
- Engineering analysis – no new worst case for Screw Torsion per ASTM F543
- Engineering analysis – no new worst case for Bending Fatigue per ASTM F382
- Engineering analysis – no new worst case for Insertion and Removal
- Engineering analysis – no new worst case for Pull-through Strength
- Engineering analysis – no new worst case for Fretting and Corrosion per ASTM F897
- Engineering analysis – no new worst case for Biocompatibility Risk Assessment per ISO 10993-1 and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" issued September 2020.

The results of engineering analyses indicate that:

- The devices performed within the intended use
- No new questions of safety or efficacy were raised
- The devices were found to be substantially equivalent to predicate devices.

CLINICAL TESTING

Clinical testing was not deemed necessary to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

Given that the proposed device has the same intended use as the predicate, Wishbone Medical Plate and Screw System, same technological characteristics to the predicate, and given the information provided in this submission, it has been demonstrated 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 device.