March 29, 2023

WishBone Medical, Inc.
Kayla Johnston
Regulatory Affairs Associate
100 Capital Drive
Warsaw, Indiana 46582

Re: K230527
Trade/Device Name: WishBone Medical Plate and Screw System
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: February 24, 2023
Received: February 27, 2023

Dear Kayla Johnston:

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)*
K230527

Device Name
WishBone Medical Plate and Screw System

Indications for Use *(Describe)*

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

The system includes Femoral Locking Plates and Screws, which are indicated for use in infant, child, and adolescent pediatric subgroups and small stature 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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In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the WishBone Medical Plate and Screw System Femoral Locking Plate System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document *The Special 510(k) Program*, issued September 13, 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	Kayla Johnston
Date Prepared	March 29, 2023
NAME OF DEVICE	
Trade or Proprietary Name	Wishbone Medical Plate & 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 Devices (OHT6), Division of Restorative, Repair and Trauma Devices (DHT6C)
Regulation	21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener. 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories (Primary)
Product Code(s)	HRS, HWC
Legally marketed device to which equivalence is claimed	Wishbone Medical Plates and Screw System-3.0mm Screws and 7-hole Straight Fibula Plate (K213489)
Other Predicate	Wishbone Medical Plates and Screws System (K180736) DePuy Synthes – Synthes Pediatric LCP Plates (K112085)
Device Description	The WishBone Medical Femoral Locking Plate System was designed to address deformity correction in the proximal and distal femur where plating is an option for correction. It is intended to be used for temporary stable internal fixation of femoral osteotomies and fractures in pediatric patients. The system consists of two plate sizes, 3.5mm and 4.5mm, which align with the corresponding screw sizes, and are offered in varying lengths based on the quantity of screw holes needed. Plates have three screw holes in the "head" of each plate, plus 3, 4, 6, 8, or 10 screw holes in the shaft of the plates, based on plate configuration. Plates are also offered in varying angles ranging from 85° to 140°, with differing offsets and flares. These variations

	allow surgeons to best match the presenting patient's anatomy. New 3.5mm and 4.5mm locking and non-locking cortical screws are being added to the system for use with these new plates. The subject Femoral Locking Plate System implants are composed of 316-Stainless Steel material (ASTM F138-19) and are supplied in one of two single-use sterile packaging configurations based on plate size: sterile packed Tyvek-covered trays or Nylon pouches, each with a double sterile barrier. The Femoral Locking Plate System is a line extension of the WishBone Medical Plate and Screw System (K180736 & K213498).
Intended Use of the Device	The WishBone Medical Plate and Screw System is intended for fixation of fractures.
Indications for Use	The WishBone Medical Plate and Screw System is indicated for pediatric and adult patients for 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, and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis. The system includes Femoral Locking Plates and Screws, which are indicated for use in infant, child, and adolescent pediatric subgroups and small stature 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 system and predicate systems have the same intended use. No new or increased risks have been identified. b. **Indications for Use:** The subject system and predicate systems have similar intended use. No new or increased risks have been identified. c. **Materials:** The subject device is manufactured from the same material as the predicate. Therefore, no new or increased risks have been identified. d. **Design Features:** The subject device design is comparable to the predicate system. No new or increased risks have been identified. e. **Sterilization:** The subject and predicate systems have the same sterilization method and dose and sterility assurance level (SAL). No new or increased risks have been identified.
PERFORMANCE DATA
NON-CLINICAL TESTING
Engineering analyses and testing were conducted on the subject Femoral Locking Plate System to reaffirm substantial equivalence with the predicate devices, addressing: • Screw Torsion

- Screw Pull-out
- Screw Insertion and Removal
- Four Point Dynamic Bend Test of Femoral Plates
- Laser Etch Location Assessment
- Biocompatibility Risk Assessment
- Sterilization Validation

CLINICAL TESTING
Clinical testing was not deemed necessary to demonstrate substantial equivalence.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA
The subject device has the same intended use and indications as the predicate Wishbone Medical Plate and Screw System (K213489 and K180736) and Synthes Pediatric LCP Plates (K112085). The subject plate also has comparable technological characteristics to the predicate device systems, and the performance data and analyses demonstrate that any differences do not raise new questions of safety and effectiveness. Therefore, we conclude that the proposed device is at least as safe and effective and performs substantially equivalent or better than the legally marketed predicate devices.