June 25, 2019

WishBone Medical
Mary Wetzel
Chief Operating Officer
1250 North Pointe Drive
Warsaw, Indiana 46992

Re: K182704
Trade/Device Name: WishBone Guided Growth System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: OBT
Dated: May 22, 2019
Received: May 23, 2019

Dear Mary Wetzel:

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 Stereotaxic, Trauma
and Restorative 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)*
K182704

Device Name
WishBone Medical Guided Growth System

Indications for Use *(Describe)*
The WishBone Medical Guided Growth System is designed for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia), valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow (humerus), radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

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 Medical Guided Growth System** 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, "Format for Traditional and Abbreviated 410(k)s", issued on August 12, 2005.

Sponsor:	**WishBone Medical, Inc.** 2150 North Pointe Dr. Warsaw, IN, 46582 Phone: +1 (574) 306-4006 Fax: (574) 376-4746 Establishment Registration Number: 3013680140
Contact:	**Mary Wetzel** Chief Operating Officer MaryWetzel@wishbonemedical.com
Date:	February 13, 2018
Subject Device:	**Trade Name:** WishBone Medical Guided Growth System **Common name(s):** bone plate, bone screw **Classification Name:** • OBT Single/multiple component metallic bone fixation appliances and accessories. (CFR 888.3030)
Primary Predicate Device:	OrthoPediatrics Pedi-Plates (K090666, K171173)
Additional Legally Marketed predicates:	Orthofix Guided Growth System Eight-Plate, Quad-Plate (K110805) WishBone Medical Plate And Screw System (K180736) BioPro Go-EZ Screw (K081149) - for packaging and sterilization BioPro Toe MP Joint (K041595) – for packaging and sterilization
Device Description:	The WishBone Medical Guided Growth System is intended to be used for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children. The WishBone Medical Guided Growth System implants are made of a 316-stainless steel material in compliance of ASTM F138, and Ti-6Al-4V Titanium alloy compliant to ASTM F136. 316 stainless steel and Ti-Al-4V are biocompatible materials that are readily available and commonly used in implanted medical devices.

Indications for Use:	The WishBone Medical Guided Growth System is designed for the express and sole purpose of redirecting the angle of growth of long bone(s). This is useful for gradually correcting angular deformities in growing children. Specific conditions/diseases for which the device will be indicated include: valgus, varus or flexion, extension deformities of the knee (femur and/or tibia), valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow (humerus), radial or ulnar deviation, flexion or extension deformities of the wrist (radius).
Summary of Technical Characteristics:	The rationale for substantial equivalence is based on consideration of the following characteristics: • **Intended Use**: same as the predicates • **Indications for Use**: all the WishBone Medical Guided Growth System indications are the same as predicate indications. • **Materials**: same as the predicates. • **Design Features**: similar to predicates. • **Sterilization**: same as BioPro predicate (K061798 and K041595)
Summary of Performance Data (Clinical & Non-clinical):	**Non-Clinical**: Engineering analysis was conducted to demonstrate substantial equivalence to the OrthoPediatrics Pedi-Plates predicate components. Cleaning testing, including endotoxin testing, was performed. **Clinical Tests**: None required as a basis for substantial equivalence.
Substantial Equivalence Conclusion:	The subject device has the same intended use and indications for use as the predicate guided growth/plating systems. The subject device has similar technical characteristics to the predicate, and the engineering analyses demonstrate that: • Any differences do not raise new questions of safety and effectiveness, and • The proposed device is expected to perform substantially equivalent to the legally marketed predicate devices.