September 18, 2020

WishBone Medical, Inc.
Mary Wentorf
VP, Quality Assurance & Regulatory Affairs
2150 North Pointe Drive
Warsaw, Indiana 46582

Re: K193368
Trade/Device Name: Smart Correction System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT, OSN
Dated: August 20, 2020
Received: August 24, 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,

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*
K193368

Device Name
Smart Correction® System

Indications for Use *(Describe)*

The Smart Correction® System is indicated for pediatric subpopulations (excluding newborns) and adults for the following:

- Joint contracture resulting in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion
- Fractures requiring distraction
- Open and closed fracture fixation, including fractures of long bones (intracapsular, intertrochanteric, supracondylar, condylar)
- Correction of bony or soft tissue defects
- Correction of bony or soft tissue deformities
- Joint arthrodesis
- Infected fractures or nonunions
- Limb Lengthening by epiphyseal or metaphyseal distraction
- Pseudoarthrosis of long bones

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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Section 5: 510(k) Summary

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 Smart Correction® 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 September 13, 2019.

1. SUBMITTER

Applicant	Name: WishBone Medical, Inc Address: 2150 North Pointe Drive Warsaw, IN 46582 Phone: (574) 306-4006 Fax: (574) 376-4746
Establishment Registration Number	3013680140
Contact	Name: Mary Wentorf Title: Vice President Quality Assurance & Regulatory Affairs Email: marywentorf@wishbonemedical.com Phone: (574) 306-4006 ext. 405
Date Prepared	12/03/2019

2. SUBJECT DEVICE

Name of Device	WishBone Medical *Smart Correction* System
Common Name	Hexapod external fixation system
Classification Name	(KTT) Application, Fixation, Nail/Blade Combination, Multiple component. Single/multiple component metallic bone fixation appliances and accessories. (21 CFR 888.3030) (OSN) Software for Diagnosis/Treatment. Single/multiple component metallic bone fixation appliances and accessories. (21 CFR 888.3030)
Product Code	KTT, OSN
Regulatory Class	Class II
510(k) Review Panel	Orthopedic Devices (OHT6)

3. PREDICATE DEVICE(S)

Primary Predicate	K970748 Smith and Nephew Taylor Spatial Frame External Fixation System
Alternate Predicate(s)	K093047 Smith and Nephew Circular Fixation System
	K141078, K143125, K152171, & K170650 Orthofix Truelok Hexapod System (TL-Hex System)

4. DEVICE DESCRIPTION

The purpose of this Traditional 510(k) is to introduce the WishBone Medical *Smart Correction* System; a multilateral hexapod circular external fixator device used to stabilize and maintain alignment of complicated fractured bones, soft tissues and/or congenital deformity repairs of an

Section 5: 510(k) Summary

extremity. The basic system consists of a minimum of two rings connected by six (6) telescopic struts that are lengthened and shortened independently. The struts' independent motion allows the surgeon to adjust the position of the proximal and distal ring. The system allows for movement in six different axes to correct difficult trauma extremity situations and/or congenital limb deformity correction. The *Smart Correction* System capitalizes on the body's natural ability of osteogenesis, guiding the orientation and position of this new bone to the desired corrected location in a steady controlled fashion. In addition to the hardware, the *Smart Correction* System has a web-based software treatment planning tool with Radiographic Navigation. The surgeon enters data from direct examination, radiographic images and the fixator parameters into the software. The software is used preoperatively to plan the reconstruction/correction and identify the frame construction. Post operatively, the surgeon enters the X-ray images and the current frame parameters to establish an adjustment schedule for the patient during the healing process.

The *Smart Correction* System is modular and facilitates a multitude of frame configurations to serve a wide variety of patient needs. Listed below are the high-level components and accessories:

- The fixator bridge is constructed of two (2) or more ring components, and each ring component is connected to another via six (6) telescopic struts. Full, 2/3, and 1/3 ring components are available, along with standard and rapid adjust struts in multiple lengths. Femoral arches and threaded rods are used as needed to provide added frame stability. Rings and femoral arches are manufactured from aluminum material; struts from titanium, stainless steel, and aluminum; and threaded rods are made from stainless steel material.
- The fixator bridge is anchored to the patient's bone by crossed tensioned wires and half pins that are secured to the rings by connector elements (wire clamps, pin clamps, cubes, bolts, nuts, washers, and twisted plates). Standard and olive wires are available, as well as multiple diameters and styles of half pins. Pins and wires may also be used to secure fragments of bone; half pins are made from stainless steel and titanium, and wires are made from stainless steel. Connector elements are manufactured out of titanium material.
- A foot ring is available and connected to the distal ring when a procedure such as ankle arthrodesis is performed. The foot rings are manufactured out of aluminum material.
- Patient comfort accessories are also included: strut ID bands (polycarbonate), foot walking attachment (POM-C), and pin/wire caps (silicone, PVC) are also included.
- The *Smart Correction* System includes reusable surgical instruments to facilitate surgical assembly of the fixator construct. The non-sterile implants and other fixator elements are contained within sterilization cases, along with the reusable instruments.

5. INDICATIONS FOR USE

Intended Use:

The WishBone Medical *Smart Correction* System is intended for use in pediatric subgroups (except newborns) and adult patients for the treatment of open and closed fractures, arthrodesis and pseudoarthrosis of long bones, limb lengthening, deformity and angular

correction, bony or soft tissue defect correction, and malunions.. This is accomplished by construction of an external fixator frame and a computer assisted planning and correction application. Based on surgeon input of examination and radiographic measurements, the software provides a schedule of adjustments for the fixator frame.

Indications for Use:

The *Smart Correction* System is indicated for pediatric subpopulations (excluding newborns) and adults for the following:

- Joint contracture resulting in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion
- Fractures requiring distraction
- Open and closed fracture fixation, including fractures of long bones (intracapsular, intertrochanteric, supracondylar, condylar)
- Correction of bony or soft tissue defects
- Correction of bony or soft tissue deformities
- Joint arthrodesis
- Infected fractures or nonunions
- Limb Lengthening by epiphyseal or metaphyseal distraction
- Pseudoarthrosis of long bones

The *Smart Correction* System indications and intended use are the same as the predicate devices. There are no significant differences in the application or clinical use of the device when used as labeled. Thus, there are no new questions of safety and effectiveness introduced by the subject device.

6. SUMMARY OF TECHNICAL CHARACTERISTICS

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 indications for use. No new or increased risks are identified.
c. **Materials**: The subject device is manufactured from similar 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 *Smart Correction* System is supplied nonsterile for the end user to sterilize in the provided sterilization cases. While the predicate system offers some pins sterile, there are pins that are provided nonsterile. The subject system has the same sterilization method for similar elements as the predicate. Therefore, no new or increased risks have been identified.

7. SUMMARY OF PERFORMANCE DATA

a. **NON-CLINICAL**: Mechanical testing, software testing, and engineering analysis was conducted to demonstrate the safety and efficacy of the *Smart Correction* System and to demonstrate substantial equivalence to the predicate components. The test reports are listed below:

- Determination and Comparison of Stiffness for Smart Correction and TSF Constructs using Wires
- Engineering Analysis of Half Pins and Wires
- Determination of In-Plane Compressive Properties of Smart Correction and TSF Rings
- Determination of Smart Correction Half Pin-Connector Joint Strength
- Evaluation of Smart Correction and TSF Bridging Element Fatigue
- Determination and Comparison of Stiffness for Smart Correction and TSF Constructs using Half Pins
- Smart Correction Foot and Ankle Frame Testing
- Smart Correction Closed Foot Ring Compression Testing
- Clinical Cleaning & Sterilization Validation Testing
- Cleaning for Biocompatibility Test
- Biocompatibility Assessment Report
- Sterilization Case Transit Test
- Sterilization Case Drop Test
- Software Validation Reports
- Software Accuracy Verifications

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

8. CONCLUSION

The subject device has the same indications/ intended use as the predicate Smith and Nephew systems (Taylor Spatial Frame External Fixation System and Circular Fixation System) and Orthofix TL-Hex System. The subject device has 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 subject device is at least as safe and effective as the legally marketed predicate devices.

Therefore, WishBone Medical's conclusion from the comparison between the subject and predicates in this document demonstrates that the *Smart Correction* System's intended use, indications, design technology features, similar medical grade materials, comparable surgical technique, and with no new safety and efficacy risks is as effective and performs equivalent to the predicate devices.