U.S. FOOD & DRUG ADMINISTRATION

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June 16, 2023

WishBone Medical, Inc.
Kellie Myers
Regulatory Affairs Manager
100 Capital Drive
Warsaw, Indiana 46582

Re: K231461
Trade/Device Name: Smart Correction System (HA Half Pins)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: May 17, 2023
Received: May 19, 2023

Dear Kellie Myers:

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,

Lixin Liu -S

Lixin Liu, Ph.D.
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231461

Device Name

Smart Correction System (HA Half Pins)

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.

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 HA Half Pins 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	Kellie Myers
Date Prepared	June 16, 2023
NAME OF DEVICE	
Trade or Proprietary Name	Smart Correction System (HA Half Pins)
Common or usual name	External Skeletal Fixation Device,
Classification Name	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
Regulatory Classification	II
510(k) Review Panel	Orthopedic Devices (OHT6)
Regulation	888.3030 Single/multiple component metallic bone fixation appliances and accessories.
Product Code(s)	KTT
Legally marketed device to which equivalence is claimed	Smart Correction System (K193368)
Reference Device	Apex Knee System Porous Coated Tibial Components (K080842)
Device Description	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 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. Post operatively, the surgeon enters the X-ray images and the current frame parameters into the software 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. Threaded rods are used as needed to provide added frame stability. Rings 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, and washers). Standard, olive wires, and threaded 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 and are made from stainless steel. Connector elements are manufactured out of titanium material. This submission also includes a line extension to add Hydroxyapatite (HA)-coated stainless steel Half Pin components. • 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 clips (PETG), 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
Intended Use of the Device	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.

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 indications for use. No new or increased risks are identified
c. **Materials**: The subject device is manufactured from similar materials to the predicate. No new or increased risks have been identified.
d. **Design Features**: The subject device design is similar to the predicate. No new or increased risks are identified.
e. **Sterilization**: The predicate Smart Correction System has some components that are offered in sterile packaging, and others that are offered non-sterile for the end user to sterilize in the provided sterilization cases. The subject HA Half Pins are offered only in sterile packaging, using the same packaging and sterilization method as several of the predicate Smart Correction sterile devices. Therefore, no new or increased risks have been identified.

PERFORMANCE DATA

NON-CLINICAL TESTING

Engineering analysis was conducted in compliance with ASTM F1541-17 Standard Specification and Test Methods for External Skeletal Fixation Devices. Evaluations conducted include:

- Construct Stiffness Test Justification

Engineering analyses were also conducted for the following:

- Clinical Cleaning & Sterilization Validation Justification
- Cleaning for Biocompatibility Justification
- Biocompatibility Assessment Justification
- Characterization and performance testing of HA coating in vendor's master file

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 for use as the predicate Smart Correction System (K193368). It also has similar technological characteristics as the predicate device, and the performance data and analyses demonstrate that any differences do not raise different questions of safety and effectiveness. Therefore, we conclude that the proposed device is at least as safe and effective and performs as well or better than the legally marketed predicate device.