DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 26, 2017

Wittenstein Intens Gmbh
% Dudley Rajapaksa
Vice President RA/QA/Technical Service
Berlin Heart Inc.
200 Valleywood Rd Suite B100
The Woodlands, Texas 77338-0

Re: K163368
Trade/Device Name: Fitbone TAA
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: November 30, 2016
Received: December 2, 2016

Dear Dudley Rajapaksa:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163368

Device Name
FITBONE® TAA

Indications for Use *(Describe)*

The WITTENSTEIN intens GmbH FITBONE® TAA intramedullary lengthening system is intended for limb lengthening of the femur and tibia.

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.

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510(K) SUMMARY

WITTENSTEIN intens GmbH
FITBONE® TAA Intramedullary Lengthening System

A. Submitter's Name and Address

Company Name:	WITTENSTEIN intens GmbH
Address:	Walter-Wittenstein-Strasse 1 97999 Igersheim, Germany
Phone:	+49 7931 493 0
Fax:	+49 7931 493 10906

B. Contact Person

Name:	Dudley Rajapaksa
Address:	200 Valleywood Rd Suite B100 The Woodlands, TX 77380
Phone:	(281) 863-9700
Fax:	(281) 863-9701

Date Prepared: 17 January 2017

C. Device Name

Proprietary Name:	FITBONE® TAA
Common Name:	Intramedullary lengthening nail

D. Classification of Device / Classification Panel/Product Code

Classification Name:	Rod, Fixation, Intramedullary and Accessories (21 CFR 888.3020)
Regulatory Class:	II
Panel:	Orthopedic Devices
Product Code:	HSB

E. Predicate Devices

Ellipse Technologies; Ellipse PRECICE® System, K131677 (primary)
Ellipse Technologies; Ellipse PRECICE® System, K131490

F. Product Description

The FITBONE® TAA system is a fully implantable intramedullary lengthening device. The FITBONE® TAA intramedullary lengthening system consists of an intramedullary lengthening nail connected to a receiver by a bipolar feed line, locking screws and an external Control Set consisting of a control electronics with a transmitter. The surgical tools and additional components are provided to facilitate the surgical process.

The FITBONE® TAA intramedullary lengthening nail is implanted into the medullary canal of the femur or tibia. The nail is connected to the bone by locking screws through longitudinal openings in the nail.

The nail consists of a telescoping system that allows it to expand. It is powered by hermetically enclosed electromagnetic motor which draws the telescope apart, during which the extension is externally steered via electronic impulses. The FITBONE® TAA intramedullary lengthening nail elongation is propelled by a highly sensitive gear and spindle mechanism which converts the rotation of the motor into an axial movement with high force.

The energy needed for the distraction process is transmitted from the outside by placing the external transmitter over the implanted receiver which is placed in the subcutaneous tissue during FITBONE® surgery. The energy transmission will be triggered by pressing the “Patient” button on the control electronics by the patient. There is no transcutaneous contact between the implanted intramedullary nail and the outer surface of the patient’s body.

G. Intended Use

The WITTENSTEIN intens GmbH FITBONE® TAA intramedullary lengthening system is intended for limb lengthening of the femur and tibia.

H. Substantial Equivalence

WITTENSTEIN intens GmbH claims the substantial equivalence of its FITBONE® TAA intramedullary lengthening system to the predicate devices based on similar indications for use, designs, and non in vitro testing performed.

The FITBONE® TAA intramedullary lengthening system as well as the predicate devices; PRECICE® intramedullary limb lengthening system (K131677 primary) and Ellipse PRECICE® intramedullary limb lengthening system (K131490) are intended for limb lengthening of the femur and tibia.

Documentation that includes mechanical test results and detailed comparison to the predicate devices demonstrates that the FITBONE® TAA intramedullary lengthening system is substantially equivalent to the Ellipse PRECICE® intramedullary limb lengthening system (K131677 primary and K131490).

The FITBONE® TAA intramedullary lengthening system and the predicate devices have similar technological characteristics. Specifically, the FITBONE® TAA system and the predicate devices are designed to be implanted into the medullary canal of the femur or tibia.

The applicant device and the predicate devices have a number of common design features, such as a telescoping rod that is attached to the bone proximally and distally using locking screws and can be lengthened non-invasively.

There are several technological differences between the applicant and predicate devices: applicant device uses electromagnetic motor to create distraction force but predicate device uses rare earth magnet, applicant device is adjusted in one direction (distraction) only and to transmit energy for distraction the external transmitter only has to be placed over the transcutaneous receiver and no special alignment is required. However these differences do not raise fundamentally new questions regarding safety and efficacy.

The FITBONE® TAA intramedullary lengthening system and the predicate devices feature similar overall shapes. The various geometrical configurations and diameters/ lengths are available to accommodate the variety of patient anatomies encountered in limb lengthening procedures. Several variants are available to accommodate the configuration and different distraction length.

I. Performance Testing

Performance of the FITBONE® TAA intramedullary lengthening system was assessed using applicable sections and methods specified in ASTM F1264: *Standard Guide for Mechanical Performance Considerations for Intramedullary Fixation Devices,* ASTM F543: *Standard Specification and test Methods for Metallic Bone Screw,* IEC 60601-1: *Medical electrical equipment-Part 1: General requirement for basic safety and essential performance* and IEC 60601-1-2: *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.*
Testing includes a usability evaluation for the Home Use of external FITBONE® Control Set by the patient.

The following specific tests (see Table 1 below) have been performed in order to establish equivalence to the predicate devices.

The nail, receiver, bipolar feed line and locking screws considered implant device with tissue/bone contact for a duration > 30 days, while the FITBONE® Control Set is skin contacting for a duration less than 24 hours.

The Pyrogenicity testing has been conducted on Implantable parts of the FITBONE® TAA intramedullary lengthening system.

The results of testing demonstrate that the WITTENSTEIN intens GmbH FITBONE® TAA intramedullary lengthening system that is the subject of this Premarket Notification is substantially equivalent to the predicate devices.

J. Conclusion

The WITTENSTEIN intens GmbH concludes, based on the information presented herein, that the FITBONE® TAA intramedullary lengthening system is substantially equivalent to similar products that have received FDA clearance and are currently legally marketed in the USA.
As described in the substantial equivalency table and supported by the extensive testing performed by the company, the WITTENSTEIN intens GmbH FITBONE® TAA intramedullary lengthening system do not raise fundamentally new questions regarding safety and efficacy.

Table 1: List of Standards

Test Description	Applicable test standard
Sterilization validation	ISO 14937
Biocompatibility testing	ISO 10993
Pyrogenicity testing	ISO 10993-11
FITBONE® Control Set: Electrical safety testing	IEC 60601-1
FITBONE® Control Set: Electromagnetic interference and compatibility testing	IEC 60601-1-2
FITBONE® Control Set: Home Use	IEC 60601-1-11
FITBONE® Control Set: Usability	IEC 60601-1-6
Locking screw: Bending fatigue testing of IMFD Locking Screws	ASTM F 1264-03
Locking screw: Torsional properties	ASTM F543-13
Locking screw: Driving torque	ASTM F543-13
Implantable rod: Static 4-point bend test	ASTM F1264-03
Implantable rod: Fatigue 4-point bend test	ASTM F1264-03
Implantable rod: Torque to failure	ASTM F1264-03
Shelf Life Validation: Requirements for materials, sterile barrier systems and packaging systems	ISO 11607-1
System functionality test	n/a
Risk management	ISO 14971