WITTENSTEIN intens GmbH
℅ Cheryl Wagoner
Consultant
Wagoner Consulting LLG
P O Box 15729
Wilmington, North Carolina 28408

February 17, 2021

Re: K203399
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 16, 2020
Received: November 19, 2020

Dear Cheryl Wagoner:

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,

Michael Owens
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.

510(k) Number *(if known)*
K203399

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.

The FITBONE®TAA intramedullary lengthening system is indicated for adult and pediatric (greater than 12 through 21 years of age) 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.

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510(K) SUMMARY

Submitter information

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Date of submission	November 18, 2020

Trade Name, Common Name, Classification

Trade Name: FITBONE® TAA
Common Name: Rod, Fixation, Intramedullary and Accessories
Classification Name: Intramedullary fixation rod
Regulation Number: 21 CFR 888.3020
Product Code: HSB
Classification: Class II
Panel code: Orthopedic

Predicate devices and reference devices

Primary Predicate	**510(k) Number**	**Manufacturer**
FITBONE® TAA	K163368	WITTENSTEIN intens GmbH
Additional Predicate		
PRECICE® Intramedullary Limb Lengthening System	K133289 - K131677	Ellipse Technologies (now: NuVasive Specialized Orthopedics Inc.)
Reference Devices		
Fassier Duval Telescopic IM Nail System	K020885	Pega Medical, Inc.
PRECICE® Plating System	K192181	NuVasive Specialized Orthopedics Inc.

Device description	The FITBONE® TAA System is a fully implantable intramedullary lengthening device. Changes to the existing FITBONE® TAA (K163368) have been introduced to extend the current portfolio by new Subject

	FITBONE® TAA09 intramedullary lengthening nail model fixed to the bone by new Subject Locking Screws and a new Subject Receiver connected to the Subject nail by a bipolar feed line with new Subject external Retraction Control Set consisting of a control electronics with a Retraction Transmitter. New Subject surgical tools are provided to facilitate the surgical process. The Subject FITBONE® TAA09 intramedullary lengthening nail model, line extension of the primary predicate FITBONE® TAA (K163368) models is implanted into the medullary canal of the femur or tibia. The nail is fixed to the bone by Locking Screws through longitudinal openings in the nail. The Subject FITBONE® TAA09 intramedullary lengthening 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 Subject FITBONE® TAA09 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 of the nail 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. The nail and Receiver are offered in sterile conditions and the Locking screws and non-implantable external electronic controlling components in non-sterile packaging configurations. The Subject FITBONE® TAA09 nail model is fixed to the bone by Locking Screws, made from Stainless steel AISI 316LVM, according to ASTM F138-13 “Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)”. Surgical procedures with the use of the Subject FITBONE® TAA09 model shall be performed with the support of orthopedic instrumentation, to facilitate their proper insertion and removal from the patient. The surgical instruments offered by WITTENSTEIN intens GmbH as part of this submission under product code: LXH (21 CFR 888.4540). The orthopedic instruments are made by medical grade stainless steel, Aluminum and Silicone. The Subject FITBONE® TAA09 and the Subject external electronic controlling components are designed to be used in the operating theatre and home environment.
Indications for use	The WITTENSTEIN intens GmbH FITBONE® TAA intramedullary lengthening system is intended for limb lengthening of the femur and tibia.

	The FITBONE®TAA intramedullary lengthening system is indicated for adult and pediatric (greater than 12 through 21 years of age) patients.
Technological Characteristics	The Subject device fundamental scientific principles and technological characteristic, including: the intended use, material and general design, are the same as, or similar to, FITBONE® TAA - K163368 and the chosen additional predicate device. Summary of the technological characteristics: ✓ *Intended use*: identical to FITBONE® TAA K163368 and additional predicate ✓ *Indications for Use, Anatomical sites, operating principles and conditions of use* are substantially equivalent to FITBONE® TAA K163368 and to the additional predicate. No new risks associated to the Subject device compared to those of the additional predicate and the reference devices which have similar indications for use, anatomical sites and conditions of use. Verification activities on Subject devices demonstrated the same safety and effectiveness performs equivalent to the predicate devices. ✓ *Material:* are equivalent as the primary predicate. ✓ *Geometry and size*: similar sizes and geometry of the nails; similar sizes and geometry of the Locking Screws. ✓ *Sterilization*: identical method as the FITBONE® TAA- K163368. The *technological characteristics* of the Subjects FITBONE® TAA are substantially equivalent to the FITBONE® TAA K163368 and predicate device.
Performance Analysis	Subject devices have similar configuration, material, sizes and design as to FITBONE® TAA K163368 and the predicate device. Results to support the determination of substantial equivalence from engineering, electrical, bench, human factors testing of the Subject devices, confirm that Subject devices are as safe, as effective, and performs as well as or better than the predicate devices. Any potential hazards of the changes introduced to FITBONE® TAA K163368 have been evaluated and controlled through Risk Management activities, and any relevant information, have been addressed in the labelling, after all control measures have been implemented.
Conclusion	Based upon equivalences in: intended use, patient population, site of application, conditions of use, operating principles, and the non-clinical performance data, the changes introduced in the FITBONE® TAA (K163368) for the new model FITBONE® TAA09 Subject nail and the additional Subject components have been shown to be safe and effective and to perform equivalently as compared to the legally marketed predicate devices. Therefore, the changes to FITBONE® TAA (K163368) for Subject devices are substantially equivalent to the legally marketed predicate devices.