Adaptable Ortho Innovations, LLC
% Kyle Kovach
Quality and Regulatory Engineer
JALEX Medical
27865 Clemens Road, Suite #3
Westlake, Ohio 44145

March 18, 2021

Re: K210285
Trade/Device Name: Adaptable Ortho Innovations Intramedullary Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: February 1, 2021
Received: February 2, 2021

Dear Kyle Kovach:

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 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)*

K210285

Device Name

Adaptable Ortho Innovations Intramedullary Nail System

Indications for Use *(Describe)*

The Adaptable Ortho Innovations Intramedullary Nail System is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non-unions.

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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ADAPTABLE ORTHO INNOVATIONS

510(k) Summary

Submitted By: Adaptable Ortho Innovations, LLC
65 Main Street
Potsdam, NY 13676

Date: 02/01/2021

Contact Person: Kyle Kovach, Quality and Regulatory Engineer
Contact Telephone: (440) 787-5832
Contact Fax: (440) 933-7839

Device Trade Name: Adaptable Ortho Innovations Intramedullary Nail System
Device Classification Name: Intramedullary Fixation Rod (21 CFR 888.3020)
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: HSB
Common Name: Rod, fixation, intramedullary and accessories

Predicate Devices: Primary Predicate: Zimmer M/DN Intramedullary Fixation System (K142281).

Reference Predicate: Synthes Tibial Nail System EX (K040762).

Reference Predicate: Ellipse Technologies Incorporated PRECICE Trauma Nail System (K152370).

Device Description:

The Adaptable Ortho Innovations Intramedullary Nail System consists of an adjustable length intramedullary nail, locking screws, and end caps. All implants are manufactured from Ti-6Al-4V ELI per ASTM F136. The nail system is available in a range of lengths and diameters to accommodate varying patient anatomy.

Indications for Use:

The Adaptable Ortho Innovations Intramedullary Nail System is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non-unions.

Comparison of Technological Characteristics with Predicate devices:

The Adaptable Ortho Innovations Intramedullary Nail System and the predicates have the same intended use and fundamental scientific technology. A comparison table of the subject device and predicate devices technological characteristics is provided in this submission in Section XIV Substantial Equivalence. A condensed comparison table is also presented below. There are no differences in technological characteristics that raise questions of safety and efficacy.

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Table 1: Dimensions and Technological Characteristics Comparison

Item	**Adaptable Ortho Innovations Intramedullary Nail System**	**Zimmer M/DN Intramedullary Fixation System (K142281)**	**Synthes Tibial Nail System EX (K040762)**	**Ellipse Technologies Incorporated PRECICE Trauma Nail System (K152370)**
Classification Name	Rod, fixation, intramedullary and accessories	Rod, fixation, intramedullary and accessories	Rod, fixation, intramedullary and accessories	Intramedullary Fixation Rod
Regulation	21 CFR 888.3020	21 CFR 888.3020	21 CFR 888.3030	21 CFR 888.3020
Product Code	HSB	HSB	JDS	HSB
Nail Lengths	Adjustable 245-290, 285-350, 345-400 mm	18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46 cm	255, 270, 285, 300, 315, 330, 345, 360, 375, 390, 405, 420, 435 mm	155, 160, 180, 195, 215, 230, 245, 275, 305, 335, 365 mm
Nail Diameters	9.5, 11.0, 13.0 mm	6, 7, 8, 9, 10, 11, 12, 13, 14, 15 mm	8.0, 9.0, 10.0, 11.0, 12.0, 13.0 mm	8.5, 10.7, 12.5 mm
Screw Lengths	25-75 mm in 5 mm increments	20-90 mm	Standard locking screws: 18-80 mm in 2 mm increments (4.0 mm diameter), 26-80 mm in 2 mm increments or 85-100 mm in 5 mm increments (5.0 mm diameter) Dual-core locking screws: 30-90 mm in 5 mm increments	20-75 mm in 5 mm increments
Screw Diameters	3.7 mm, 4.5 mm	4.2, 3.7 mm	Standard locking	3.5, 4.0, 5.0 mm

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			screws: 4.0, 5.0 mm Dual-core locking screws: 3.4, 4.3 mm	
Material	Ti-6Al-4V ELI per ASTM F136	Stainless steel	Titanium alloy	Ti-6Al-4V ELI per ASTM F136
System Implanted Components	Proximal and distal nail shafts, locking nut, locking screws, nail cap	Cannulated intramedullary nail, locking screws, nail cap, cortical nuts and washers	Cannulated tibial nail, locking screws and bolts, endcap	Trauma nail containing rare earth magnet, telescoping lead screw/nut assembly, and planetary gearing, locking screws, end cap
Adjustable Nail Length?	Yes	No	No	Yes
Implant Location	Tibia	Tibia, Femur, Humerus	Tibia	Tibia, Femur, Humerus

The subject and predicate devices compare similarly in the dimensions and materials of their nails and screws and are all intended for implantation into the tibia.

The Adaptable Ortho Innovations Intramedullary Nail System is comprised of two nail shaft components, which are threaded together prior to distribution and locked in place by a locking nut during surgery. Once the pre-assembled proximal and distal shafts are adjusted to the desired total length and permanently locked together, the Adaptable Ortho nail is substantially equivalent in form and function to the predicate devices, which utilize a single-piece nail shaft. Both the subject and predicate devices are secured into the bone by locking screws, and capped at the proximal end with an optional nail (end) cap.

Clinical and Non-Clinical Testing:
All Adaptable Ortho Innovations Intramedullary Nail System implants are delivered sterile and a gamma irradiation sterilization validation was performed to validate the sterilization dose and ensure a Sterility Assurance Level (SAL) of 10^{-6}. Instruments are not provided as part of the system and are intended to be obtained by the user as a general orthopedic instrument set for intramedullary nail insertion. Any instruments chosen should be cleaned and sterilized per the instructions for use specific to those instruments.

Packaging validation was performed to validate a 1 year shelf life for the Adaptable Ortho Innovations Intramedullary Nail System implant through real-time and accelerated aging techniques. The validation study also validated the integrity of the packaging following sterilization and distribution testing.

Clinical testing was not required for this device. Substantial equivalence to the predicate devices was determined through comparison of mechanical testing results, materials, indications and intended uses, and device function.

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Substantial equivalence is supported by the results of mechanical testing including static 4-point bending, static torsion, static axial compression, dynamic axial compression, and dynamic bending fatigue (for both the nail and screw components of the system) per ASTM F1264 and ASTM F543. Mechanical testing methods, data, and reports are provided in this submission.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate devices, the subject devices have demonstrated substantial equivalence.