Smith & Nephew
Allison Chan
Regulatory Affairs Specialist II
1450 E Brooks Rd.
Memphis, Tennessee 38116

October 13, 2017

Re: K163653
Trade/Device Name: NOVOS-NAIL Limb Lengthening System (LLS)
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 22, 2017
Received: September 25, 2017

Dear Allison Chan:

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 (DICE) 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 (DICE) 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)*

K163653

Device Name

NOVOS-NAIL Limb Lengthening System

Indications for Use *(Describe)*

The NOVOS-NAIL Limb Lengthening System is indicated 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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Submitted by:	Smith & Nephew, Inc. Advanced Surgical Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 10,2017
Contact Person and Address:	Allison Chan Regulatory Affairs Specialist II T 901-399-1098 F 901-566-7022
Name of Device:	Smith & Nephew, Inc. NOVOS-NAIL Limb Lengthening System
Common Name:	Intramedullary Nail
Device Classification Name and Reference:	21 CFR 888.3020, Intramedullary fixation rod
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	HSB (Rod, Fixation, Intramedullary and Accessories)

Device Description

The Smith & Nephew NOVOS-NAIL Limb Lengthening System (NOVOS-NAIL LLS) is composed of a modular implantable intramedullary rod, locking screws, and an external actuator. The modular implantable rod is available in different configurations, lengths, and diameters to accommodate a variety of patient anatomies. The system uses locking screws and nail caps (optional) previously cleared with the TRIGEN Nail system (K981529).

The NOVOS-NAIL implant includes an enclosed rare earth magnet, telescoping lead screw/nut assembly and gearing. The subject device is supplied sterile by gamma sterilization. The external actuator is supplied non sterile.

Intended Use

The NOVOS-NAIL Limb Lengthening System is indicated for limb lengthening of the femur and tibia.

Comparison of Technology Characteristics with the Predicate Device

The NOVOS-NAIL Limb Lengthening System is substantially equivalent in design and fundamental scientific technology to the defined predicate and does not raise any new issues of safety and efficacy. At a high level, the subject and predicate devices are based on the following same technological elements

- Limb lengthening for tibia and femurs
- Implanted in the intramedullary canal

The following technological differences exist between the subject and predicate device.

- Ability to shorten nail if the rod has been distracted too far
- Use of external device to control interaction of rare earth magnet
- Manufactured from 20Cr-15Ni-40Co-7Mo-16Fe

Summary of Pre-Clinical Testing

The following performance data was provided in support of the substantial equivalence determination:

- *Finite Element Analysis (FEA)* – FEA of the 8mm and 11mm NOVOS Limb Lengthening Nails using Retrograde Femoral and Antegrade Tibial Loading Modes- Finite Element analysis evaluated the structural strength of the subject devices in retrograde femur and antegrade tiba loading configurations.
- *Construct Fatigue Testing*- Construct fatigue testing was conducted on the 8mm and 11mm NOVOS-NAIL and the predicate device. Results of the testing have determined that the subject devices would have equivalent construct fatigue performance compared to the predicate.
- *Bending Fatigue Evaluation*- Testing was conducted to evaluate the bending fatigue performance of the 8mm and 11mm NOVOS- NAIL and to determine potential failure modes for the nail. Results of the testing have determined that the subject devices would have similar bending fatigue performance as compared to the predicate.
- *Distraction Accuracy*-Testing evaluating the accuracy of the actuator and the distraction mechanism in the NOVOS-NAIL was conducted for both the 8mm and 11mm nail. Results of the testing have shown the subject devices have met the acceptance criteria for distraction accuracy.
- *Usability Testing*- A human factors validation was conducted to evaluate the usability of the NOVOS-NAIL LLS. Results of the usability study have shown that any residual use-related risk that remain after human factors testing are low and are outweighed by the benefits derived from the device.
- *Bacterial Endotoxin Testing:* Testing was completed and found to have the met the acceptable endotoxin limits as stated in the FDA Guidance*, "* Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," and "Pyrogen and Endotoxin Testing: Questions and Answers," and ANSI/AAMI ST72.
- *Static Bend Strength:* Testing was conducted to evaluate the static bend performance of the 8mm and 11mm NOVOS-NAIL in a static three point bend test. Results of the testing have shown the subject devices demonstrate adequate static bending performance during the expected clinical use.

Substantial Equivalence Information

The substantial equivalence of the NOVOS-NAIL Limb Lengthening Nail System is based on similarities in intended use, indications for use, overall design, and performance to the predicate systems listed in the following table.

Table 5.1: Substantially Equivalent Predicates to the NOVOS Limb Lengthening Nail System

Design Aspect Reviewed	NOVOS-NAIL Limb Lengthening Nail System	Intramedullary Skeletal Kinetic Distractor (ISKD)-*Primary Predicate*	Precice Intramedullary Limb Lengthening System-*Reference Predicate*
510(k) Number	Subject 510(k)	K010322	K101997
Manufacturer	Smith & Nephew	OrthoDyne, Inc.	Ellipse Technologies, Inc.
Similar Indications for Use	Yes	Yes	Yes
Sterilization Methods	Gamma	Ethylene Oxide	Gamma
Nail Diameter	8mm, 11mm	10.7mm	8.5mm, 10.7mm, and 12.5mm
Cross Section Shape	Circular	Circular	Circular
Rate of Lengthening	Physician to determine rate. Dependent upon patient activity level; 1mm/day	Physician to determine rate. Dependent upon patient activity level; .75-1.25mm/day	Physician to determine rate, dependent upon patient activity level ~1mm /day.
Control of Lengthening	External Actuator	Patient's activity level, I.e. rotational oscillations of the limb	External remote controller
Monitoring of Distraction	X-ray for confirmation	External hand held monitor	X-ray for confirmation

Design Aspect Reviewed	NOVOS-NAIL Limb Lengthening Nail System	Intramedullary Skeletal Kinetic Distractor (ISKD)-*Primary Predicate*	Precice Intramedullary Limb Lengthening System-*Reference Predicate*
Safety Features	Length of rod is able to be shortened by rotating the external actuator	Automatic stop when predetermine length is achieved; one-way clutch design	Length of rod is able to be shortened from the external remote controller
Material	20Cr-15Ni-40Co-7Mo-16Fe	Ti-6Al-4V	Ti-6Al-4V
Method of Fixation	4.5mm & 5.0mm Internal Hex Captured Screws (K981529)	4.0mm & 4.8mm diameter locking screws	Locking Pegs

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the NOVOS-NAIL Limb Lengthening Nail System. Based on the similarities to the predicate components and a review of the mechanical testing performed, the devices are substantially equivalent to above predicate systems.