August 7, 2025

Ortho Solutions UK Ltd.
Alex Faley
Product Development Engineer
West Station Business Park, Spital Road, Unit 5
Maldon, ESS CM9 6FF
United Kingdom

Re: K250622
Trade/Device Name: Succession™ AFN System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: July 7, 2025
Received: July 7, 2025

Dear Alex Faley:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2025.08.07 08:26:01 -04'00'

for: Farzana Sharmin, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250622

Please provide the device trade name(s).

Succession™ AFN System

Please provide your Indications for Use below.

The Succession™ Ankle Fusion Nail (AFN) System is a tibiotalocalcaneal (TTC) solid fusion system that has been developed for the following indications:

- Failed ankle replacement
- Arthritis of ankle and subtalar joint
- Correcting neuromuscular imbalance of hindfoot, where bone fusion is required
- Revision of failed ankle and/or subtalar fusion
- Revision of failed Tibiotalocalcaneal (TTC) fusion
- Talar Avascular Necrosis (AVN)
- Charcot
- Trauma
- Neuroarthropathy
- Pseudoarthrosis
- Rheumatoid arthritis

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Contact Details:

Applicant Name: OrthoSolutions UK Ltd.

Applicant Address: West Station Business Park, Spital Road, Unit 5 Maldon ESS CM9 6FF United Kingdom

Applicant Contact: Mr. Alex Faley

Applicant Contact Email: alex.faley@orthosol.com

Applicant Contact Telephone: 419-577-9296

Device Name:

Device Trade Name: Succession™ AFN System

Common Name: Rod, Fixation, Intramedullary and Accessories

Classification Name: Intramedullary Fixation Rod

Regulation Number: 888.3020

Product Code: HSB

Legally Marketed Predicate Devices:

Predicate Number: K121575 (Primary Predicate)
Predicate Trade Name: Oxford™ Ankle Fusion Nail (AFN) System

Predicate Number: K173811 (Secondary Predicate)
Predicate Trade Name: In2Bones TriWay® Tibiotalocalcaneal (TTC) Arthrodesis System

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Device Description Summary:

The Succession™ AFN System is comprised of a set of straight 10mm, 11mm, and 12 mm diameter cannulated nails, 12.5mm diameter end caps, 5mm and 6mm diameter cortical screws, and accessory instrumentation. All implants are composed of Titanium (Ti-6Al-4V ELI) and provided to the user sterile packed with a combination of both sterile and non-sterile accessory instrumentation to assist in implantation. Each of the accessory instruments provided with the subject device contain substantially equivalent materials to the Oxford™ Ankle Fusion Nail System predicate device instrumentation, including stainless steel (ASTM F899 and ASTM F138 / ISO 5832-1) and Fluorinated Ethylene Propylene direct contacting materials.

During the procedure, following preparation of the tibial intramedullary canal (using the device accessory instrumentation) and placement of the intramedullary fixation nail, the provided 5mm screws are inserted into the medial to lateral (M/L) slots of the implant, allowing for fixation in the tibia, talus, and calcaneus. In both the talus and calcaneus, dynamic compression slots are included in the nail and are to be used with the internal and/or external methods of compression across the tibiotalar and subtalar joints. In addition, a 6mm screw is placed through the only angled posterior to anterior (P/A) slot located at the distal end of the nail implant, allowing for additional fixation between the calcaneus and talus. Following the placement of all screws, the end caps are implanted to add stability to the distal end of the nail and prevent excess bony ingrowth from occurring within the nail cannulation. Overall, the Succession™ Ankle Fusion Nail is intended to effectively fuse the tibiotalar and subtalar joints together, providing stability in the hindfoot region to facilitate tibiotalocalcaneal arthrodesis.

Intended Use/Indications for Use: The Succession™ Ankle Fusion Nail (AFN) System is a tibiotalocalcaneal (TTC) solid fusion system that has been developed for the following indications:

- Failed ankle replacement
- Arthritis of ankle and subtalar joint
- Correcting neuromuscular imbalance of hindfoot, where bone fusion is required
- Revision of failed ankle and/or subtalar fusion
- Revision of failed Tibiotalocalcaneal (TTC) fusion
- Talar Avascular Necrosis (AVN)
- Charcot
- Trauma
- Neuroarthropathy
- Pseudoarthrosis
- Rheumatoid arthritis

Indications for Use Comparison: Other than the system name, there are no changes to the device Indications for Use Statement in comparison to the predicate.

Technological Comparison: The Subject device is substantially equivalent to the OrthoSolutions Oxford™ (now called Oxbridge™) Ankle Fusion Nail System (*Primary Predicate - K121575*) and In2Bones TriWay® Tibiotalocalcaneal (TTC) Arthrodesis System predicates (*Secondary Predicate - K173811*) and the new components do not raise any different questions regarding the device safety or effectiveness. The subject device has the same technological characteristics as the original Oxbridge™ device including the same materials, chemical composition, manufacturing methods, and a similar size range. Other than the change in trade name, there are no substantial changes to the device labeling.

The subject device utilizes the same sterilization method (gamma irradiation) and equivalent implant packaging as the original primary predicate device. Likewise, the new sterile accessories will utilize the same sterilization method (gamma irradiation) and equivalent implant packaging as the Oxbridge™ sterile accessories. The new non-sterile Succession™ class 1 accessory

instrumentation will utilize the same method of sterilization as the non-sterile predicate device accessory instrumentation - Steam Sterilization.

The shelf-life of the subject Succession™ device is equivalent to the predicate OrthoSolutions Oxbridge™ device.

The subject device will utilize a similar set of class 1 accessory instrumentation with the addition of an extraction adapter, new Hudson connection handles, an impactor, and an external compression instrument (for optional use).

There are no new materials that directly contact the body and/or tissue, new points of contact between dissimilar metals, or novel manufacturing techniques/processes being introduced into the subject system. Therefore, there are no significant changes to device biocompatibility.

Non-Clinical and/or Clinical Tests Summary:

Mechanical Testing was completed on the screw implant devices per ASTM F543 Annex A1 through Annex A4. The results of these tests indicated that the Succession™ device cortical screws are substantially equivalent with regards torsional yield strength, driving torque, pullout strength, and self-tapping force.

Cyclic Fatigue Testing was completed on the nail device (Oldenburg G, Kaschner H, DiCiccoJ, et al.). The results of this analysis indicated that the Succession™ nail device is substantially equivalent with regards to fatigue strength.

Comparative analyses were completed to address the bending and torsional strength of the nail, the bending strength of the screws, and the corrosion resistance of the worst-case components, with all results indicating that the subject Succession™ device is substantially equivalent to the predicate device.

Conclusions:

In conclusion, the components that are the subject of this 510(k) are substantially equivalent to the K121575 Ortho Solutions Oxford™ Ankle Fusion Nail System (now called the Oxbridge™ Ankle Fusion Nail System) and the new Succession™ components do not raise any different questions regarding the safety or effectiveness of the device.