February 23, 2024

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

Re: K240212
Trade/Device Name: COGNiTiON™ Staple System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: January 16, 2024
Received: January 25, 2024

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.

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,

Limin Sun -S

Limin Sun, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240212

Device Name

COGNiTiON Staple System

Indications for Use *(Describe)*

The Ortho Solutions COGNiTiON™ Staple System is indicated for hand and foot bone fragments, osteotomy, fixation and joint arthrodesis. The COGNiTiON™ Staple System is not intended for spinal use.

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.

510(k) Summary

Contact Details:

Applicant Name: Ortho Solutions UK Ltd.

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

Applicant Contact Telephone: 419-577-9296

Applicant Contact: Mr. Alex Faley

Applicant Contact Email: alex.faley@orthosol.com

Device Name:

Device Trade Name: COGNiTiON™ Staple System

Common Name: Single/multiple component metallic bone fixation appliances and accessories

Classification Name: Staple, Fixation, Bone

Regulation Number: 888.3030

Product Code: JDR

Legally Marketed Predicate Devices:

Predicate Number: K111678

Predicate Trade Name: Ortho Solutions Extremity Fixation Implants for Osteosynthesis

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Device Description Summary:

The COGNiTiON Staple System is comprised of a set of implantable metallic (Superelastic NiTi Alloy per ASTM F2063) staples and accessory instrumentation. The system consists of a series of two and four-leg staples of various bridge and leg lengths. Each staple is provided to the user in a relaxed state with the staple legs in a converging position. During the staple insertion step, the provided staple driver is used to splay the staple legs, allowing for implantation across the fracture, fusion, or osteotomy site. The staple legs then have the inherent propensity to converge due to the superelastic nature of the NiTi material. This stability is intended to allow for bone healing to occur.

Intended Use/Indications for Use: The Ortho Solutions COGNiTiON™ Staple System is indicated for hand and foot bone fragments, osteotomy, fixation and joint arthrodesis. The COGNiTiON™ Staple System is not intended for spinal use.

Indications for Use Comparison: The overall content of the indications for use of the subject device is substantially equivalent to the predicate device (per K111678) when comparing the overall intentions of the system, with the subject device's indications for use statement being simplified to exclude the indication of fixating soft tissue to bone. Through post market monitoring that OrthoSolutions has completed, we know that the predicate staple system is not being used for the fixation of soft tissue to bone. Otherwise, the content/meaning of the latest indications for use statements are identical with both the subject and the predicate device being indicated for hand and foot bone fragments, osteotomy, fixation and joint arthrodesis.

Technological Comparison: The components that are the subject of this 510(k) are substantially equivalent to the K111678 Ortho Solutions Extremity Fixation Implants for Osteosynthesis predicate and the new components do not raise any new issues of safety or effectiveness. The subject device has the same technological characteristics as the original device including the same materials, chemical composition, manufacturing methods, austenite finish temperature, and a similar size range as the Ortho Solutions predicate. Other than the change in trade name, there are no substantial changes to the device labeling.

The new implants utilize the same sterilization method and equivalent implant packaging as the original device. The new COGNiTiON class 1 accessory instruments will utilize the same method of sterilization as the predicate Memo device instruments - Steam Sterilization.

The shelf-life of the subject COGNiTiON staples is equivalent to the predicate Ortho Solutions Memo Staples.

The new staples utilize a similar set of class 1 accessory instrumentation with the addition of a countersink, k-wires and an osteotome.

There are no new patient contacting materials, new points of contact between dissimilar metals, or alternative manufacturing techniques/processes being introduced into the subject system that were not previously included in the predicate Ortho Solutions device. Therefore, there are no changes to device biocompatibility.

Non-Clinical and/or Clinical Tests Summary & Conclusions: Mechanical Testing was completed per ASTM F564 Annex A1 and Annex A4. Corrosion testing was completed per ASTM F2129-19a. The results of these tests indicated that the COGNiTiON device is superior with regards to static bending strength, constant amplitude bending resistance, and corrosion resistance.