April 26, 2024

Ortho Life Systems Private Limited
Tamandeep Kochhar
Director
D-111, Okhla Industrial Area, Phase 1
New Delhi
Okhla, Delhi 110020
India

Re: K233873
Trade/Device Name: XLO Brand of Locking Distal Humerus Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 28, 2024
Received: March 28, 2024

Dear Tamandeep Kochhar:

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,

Shumaya Ali -S

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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.

510(k) Number *(if known)*
K233873

Device Name
XLO Brand of Locking Distal Humerus Plating System

Indications for Use *(Describe)*
The XLO Brand of Locking Distal Humerus Plating System is indicated for intra-articular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus.

The system is indicated for use in adult patients only. All implants are for single use only.

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.

K233873
510(k) Summary

Premarket Notification 510(k) Summary as required by Section 807.92

General Company Information as required by 807.92 (a)

(a.1). The submitter's name, address, telephone number, a contact person, and the date the summary was prepared

Submitter's Name: Ortho Life Systems Pvt. Ltd.

Address: D-111, Okhla Industrial Area, Phase 1, New Delhi-110020, India

Contact Person Name: Mr. Tamandeep Singh Kochhar

Title: Director

Phone Number: +91-11-41324393

Dated: April 25, 2024

Throughout the submission there is a mention of XLO Brand of Locking Distal Humerus Plating System that represents the range of products covered under this 510(k) submission.

(a.2). The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Proprietary Name:

- XLO Brand of Locking Distal Humerus Plating System

Common or Usual Name:

- PLATES, FIXATION, BONE
- SCREWS, FIXATION, BONE

Classification Name:

- Orthopedic Bone Plates
- Orthopedic Bone Screws

Classification Product Code:

HRS, HWC

Device Class: II

Review Pane: Orthopedic

Regulation Description:

- Single/multiple component metallic bone fixation appliances and accessories
- Smooth or threaded metallic bone fixation fastener

Regulation Number: 21 CFR 888.3030 (primary) and 21 CFR 888.3040

(a.3). Identification of the Predicate Device:

Following are the predicate device 510(k) with which we are claiming substantial equivalence:

Primary Predicate Device:

- Synthes Variable Angle LCP Elbow System (K120717)

Additional Predicate Devices:

- Synthes 3.5mm LCP Distal Humerus System (K033995)
- Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684)
- Synthes Cortical Screws (K112583)

(a.4). A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device

Device Description:

Plate Fixation System

The XLO Brand of Locking Distal Humerus Plating System consists of various shape and sizes of plates featuring compression and locking or non-locking holes, full threaded-cortical, locking or non-locking & self-tapping screws. The XLO Brand of Locking Distal Humerus Plating System consists of the following implants:

- Distal Humerus Locking Plate 2.7/3.5, Dorsolateral, Left & Right
- Distal Humerus Locking Plate 2.7/3.5, Dorsolateral, With Lateral Support Left & Right
- 3.5mm cortical screw
- 2.7mm locking screw
- 3.5mm locking screw

The aforementioned plates are used with cortical screws & locking Screws.

These bone plates are generally designed on the basis of the bone contour and anatomy.

The plates and screws are fabricated from titanium-alloy (Ti-6Al-4V).

These implants are sold non-sterile, the products have to be sterilized prior to use.

(a.5). A statement of the intended use of the device

Indications for Use:

The XLO Brand of Locking Distal Humerus Plating System are indicated for intra-articular fractures of the distal humerus, comminuted supracondylar fractures, osteotomies, and non-unions of the distal humerus.

The system is indicated for use in adult patients only. All implants are for single use only.

(a.6). Summary of Technological Characteristics as compared to the predicate devices:

Substantial equivalence including comparison with predicate devices

A comparison between the XLO Brand of Locking Distal Humerus Plating System and predicate devices has been performed which has resulted in demonstration of similarities in dimensional and performance criteria.

Following is the summary of parameters in which the comparison has been verified:

S. No.	Characteristics	Predicate Device Versus New Device (XLO Brand)	Remarks
01	Indications for use	Same intended use and similar Indications for Use in New Device and Predicate device	Equivalent
02	Material	Same material used in New Device and Predicate device	Equivalent
03	Performance Standards	Same performance standards used in both New Device as well as predicate device	Equivalent
04	Dimensional Verification	Same dimensions found in both New Device as well as Predicate device	Equivalent

(b.1): Discussion on the non-clinical testing performed

Following are the applicable product standards considered for non-clinical standards

A: Material Standards

B: Performance Standards

A: Material Standards:

The following material standards were used to manufacture the subject metallic surgical implants.

1. ASTM F136: Standard specification for wrought Titanium-6Aluminium-4Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.

We have verified the purchased material is in compliance with these standards.

B: Performance Standards:

The device performance of XLO Brand of Locking Distal Humerus Plating System has been demonstrated against following applicable standards

- ASTM F382,
- ASTM F543.

The subject device test results were compared to the performance criteria outlined in FDA guidance documents, "Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway" and "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway".

(b.2). Discussion on the clinical evaluation referenced and relied upon:

Clinical data and conclusions were not needed for these devices to demonstrate substantial equivalence to the predicate devices.

(b.3). CONCLUSION:

General, Safety and Performance conclusion:

S. No.	**Parameter of Conclusion**	**Proposed Device**	**Predicate Device**
01	Product Code	For Bone Plates: HRS For Bone Screws: HWC	Same
02	Regulation Number	For Bone Plates: 21CFR 888.3030 For Bone Screws: 21CFR 888.3040	Same
03	Regulatory Class	Class II	Same
04	Intended Use	Same as mentioned in Point (a.6) above.	Same Intended Use
05	Sterilization	Provided Non-Sterile and to be sterilized using Moist Heat Sterilization Method to achieve SAL of 10^{-6} as validated per ANSI/AAMI/ISO 17665-1:2006/(R) 2013, *Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation, and control of a sterilization process for medical devices.*	Same

06	Mechanical Test Performance	**For Bone Plates:** Subject device plates were tested per ASTM F382 Static Four Point Bend Test. The test results conform to the performance criteria outlined in FDA guidance document, "Orthopedic Fracture Fixation Plates – Performance Criteria for Safety and Performance Based Pathway". **For Bone Screws:** Subject device screws were tested per ASTM F543 for Torsional Strength, Driving Torque, Removal Torque, and assessed for Axial Pull-out Strength. The results conform to the performance criteria outlined in FDA guidance document, "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway".	Same
07	Material Standards	ASTM F136	Same

From the available data available we can justify that the XLO Brand of Locking Distal Humerus Plating System are as safe, as effective and perform as same indications for use as that of already marketed predicate devices identified in (a.3) of 510(k) summary.

Hence our devices can be considered safe and effective for their intended use.