July 25, 2025

Zimmer Biomet
Sonayya Achalla
Senior Specialist, Regulatory Affairs
56 East Bell Drive
P.O.Box 587
Warsaw, Indiana 46581

Re: K251620
Trade/Device Name: A.L.P.S. Proximal 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
Dated: May 27, 2025
Received: May 27, 2025

Dear Sonayya Achalla:

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,

Thomas Mcnamara -S

For: Christopher Ferreira, MS
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.

Submission Number *(if known)*

K251620

Device Name

A.L.P.S. Proximal Humerus Plating System

Indications for Use *(Describe)*

The A.L.P.S Proximal Humerus Plating System is indicated for fixation of fractures and fracture dislocations, fusions, osteotomies and non-unions of the humerus, particularly in osteopenic bone.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) #: K251620

510(k) Summary

Prepared on: 2025-05-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Zimmer Biomet
Applicant Address	56 East Bell Drive P.O.Box 587 Warsaw IN 46581 United States
Applicant Contact Telephone	+1(574)373-0320
Applicant Contact	Mr. Sonayya Achalla
Applicant Contact Email	sonayya.achalla@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	A.L.P.S. Proximal Humerus Plating System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K143697	Biomet Proximal Humerus Plating System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The A.L.P.S. Proximal Humeral Plating System is made from a titanium alloy and is available in configurations for both the left and right sides, as well as in various lengths. This system includes both locking and non-locking screws/pegs, along with multidirectional screws crafted from titanium alloy and cobalt chromium. It comes complete with general orthopedic instrumentation and system-specific instruments designed for use during implant installation.

Implants are available in both gamma-sterilized and non-sterile options. The disposable instruments are provided only in a sterile condition, while the reusable instruments are offered non-sterile, allowing users to perform steam sterilization before use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The A.L.P.S Proximal Humerus Plating System is indicated for fixation of fractures and fracture dislocations, fusions, osteotomies and non-unions of the humerus, particularly in osteopenic bone.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications are similar between the predicate and the subject device.

Technological Comparison

21 CFR 807.92(a)(6)

Comparison of Technological Characteristics:
The A.L.P.S Proximal Humerus Plating System are similar in intended use and similar in basic shape, material and performance

characteristics to the predicate device. There is no change in the fundamental scientific technology shared by both the subject device and predicate device and therefore the technological characteristics do not raise any new questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Plates:
- Implant Construct Axial Load Static Testing
- Implant Construct Axial Load Fatigue Testing

Screw & Peg:
- Screw and Peg Performance Testing

Clinical data and conclusions were not needed for this device.

The proposed device has a similar intended use as the predicates and similar technological characteristics. The information provided herein demonstrates that:
• any differences do not raise any different questions of safety and effectiveness; and
• the proposed device is at least as safe and effective as the legally marketed predicate devices.