



February 19, 2025

Biomet Orthopedics
Prerna Satavase
Regulatory Affairs Sr Specialist
56 E Bell Drive
Warsaw, Indiana 46581

Re: K243761

Trade/Device Name: A.L.P.S. Small Fragment 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, HTN, HWC
Dated: December 6, 2024
Received: February 5, 2025

Dear Prerna Satavase:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.

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

Indications for Use

Submission Number (if known)

K243761

Device Name

A.L.P.S. Small Fragment Plating System

Indications for Use (Describe)

The A.L.P.S. Small Fragment Plating System is intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.

The 100 Degree Tubular Plate is intended for fixation of fractures, osteotomies and non-unions of the olecranon, humerus, radius, ulna, distal tibia (including intra-articular), fibula, particularly in osteopenic bone.

Washers are intended to be used in conjunction with bone screws.

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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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	A.L.P.S. Small Fragment 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, HWC, HTN

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K111663	TRAUMA INTERNAL FIXATION SYSTEMS	HRS
K072083	SMALL FRAGMENT LOCKING PLATING SYSTEM	HRS
K920738	ACE 100 DEGREES TUBULAR PLATE	HRS
K895107	ACE ORTHOPAEDIC WASHERS	HTN
K083843	LOCKING ANATOMIC & COMPOSITE PLATING SYSTEM	HRS

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The A.L.P.S.® Small Fragment System is a titanium alloy (Ti-6Al-4V) plate and screw system that fuses locking screw technology with conventional plating techniques. The subject device consists of plates, screws, and washers. The devices are available in sterile and non-sterile options, and vary by sizes and number of holes, making the device suitable for a wide range of patient anatomy and needs.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The A.L.P.S. Small Fragment Plating System is intended for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.

The 100 Degree Tubular Plate is intended for fixation of fractures, osteotomies and non-unions of the olecranon, humerus, radius, ulna, distal tibia (including intra-articular), fibula, particularly in osteopenic bone.

Washers are intended to be used in conjunction with bone screws.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

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

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Comparison of Technological Characteristics:

The A.L.P.S. Small Fragment Plating System is similar in intended use and similar in basic shape, material and performance characteristics to the predicate devices. 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 different questions of safety and effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Evaluation of MR compatibility to support MR Conditional labeling

- RF Heating- ASTM F2182
- Displacement Force- ASTM F2052
- Magnetic Torque- ASTM F2119
- Image Artifact- ASTM F2213

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.