March 24, 2026

Aap Implantate AG
% Kevin Thomas
Vice President & Director of Regulatory Affairs
PaxMed International, LLC
1925 Palomar Oaks Way, Suite 210
Carlsbad, California 92008

Re: K254253
Trade/Device Name: LOQTEQ® VA Proximal Humerus Plate 3.5
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: December 29, 2025
Received: December 29, 2025

Dear Kevin Thomas:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

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)*

K254253

Device Name

LOQTEQ® VA Proximal Humerus Plate 3.5

Indications for Use *(Describe)*

LOQTEQ® VA Proximal Humerus Plate 3.5 is indicated for fractures and fracture dislocations, osteotomies, and nonunions of the proximal 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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# 510(k) Summary
# K254253
# LOQTEQ® VA Proximal Humerus Plate 3.5
# *aap* Implantate AG

March 12, 2026

## ADMINISTRATIVE INFORMATION


| | |
|---|---|
| Manufacturer Name | *aap* Implantate AG<br>Lorenzweg 5<br>12099 Berlin Germany<br>Telephone +49 30 750 19 0 |
| Official Contact | Andreas Reuter<br>Director of Research and Development Trauma, and Regulatory Affairs |
| Representative/Consultant | Kevin A. Thomas, PhD<br>Rebecca E. Kattan, PhD<br>Floyd G. Larson, MS, MBA<br>PaxMed International, LLC<br>1925 Palomar Oaks Way, Suite 210<br>Carlsbad, CA 92008<br>Telephone +1 858-792-1235<br>Email kthomas@paxmed.com<br>rkattan@paxmed.com<br>flarson@paxmed.com |


## DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Device Name | LOQTEQ® VA Proximal Humerus Plate 3.5 |
| Common Name | Plate, Fixation, Bone |
| Primary Product Code | HRS – Plate, Fixation, Bone |
| Regulation Number | 21 CFR 888.3030 |
| Regulation Name | Single/multiple component metallic bone fixation appliances and accessories |
| Regulatory Class | Class II |
| Secondary Product Code | HWC – Screw, Fixation, Bone |
| Regulation Number | 21 CFR 888.3040 |
| Regulation Name | Smooth or threaded metallic bone fixation fastener |
| Regulatory Class | Class II |
| Classification Panel | Orthopedic |
| Reviewing Division | Office of Orthopedic Devices (OHT6)<br>Division of Restorative, Repair and Trauma Devices (DHT6C)<br>Restorative, Repair and Trauma Devices |

## PREDICATE DEVICE INFORMATION

Primary Predicate Device
K211582, LOQTEQ® Proximal Humerus Plate 3.5 System, *aap* Implantate AG

Reference Devices
K121495, LOQTEQ® Proximal Humerus Plate 3.5 System, *aap* Implantate AG
K041860, Synthes (USA) LCP® Proximal Humerus Plates, Long, Synthes (USA)

K230141, LOQTEQ® VA Elbow Plates 2.7/3.5 System, *aap* Implantate AG
K113652, *aap* LOQTEQ® Small Fragment Set, *aap* Implantate AG
K233008, Cannulated Headless Bone Screws, *aap* Implantate AG

## INDICATIONS FOR USE STATEMENT

LOQTEQ® VA Proximal Humerus Plate 3.5 is indicated for fractures and fracture dislocations, osteotomies, and nonunions of the proximal humerus, particularly in osteopenic bone.

## SUBJECT DEVICE DESCRIPTION

The subject device LOQTEQ® VA Proximal Humerus Short Plates are 21.5 mm wide at the proximal end, 12.4 mm wide along the shaft, and 3.2 mm thick. The shaft of each of the subject device short plates has one (1) oblong, non-locking screw hole, and 2, 3, 4, 5, or 6 VA (variable angle) locking 3.5 mm screw holes.

The subject device LOQTEQ® VA Proximal Humerus Long Plates are 21.5 mm wide at the proximal end, 12.8 mm wide along the shaft, and 3.9 mm thick. The shaft of each of the subject device long plates has one (1) oblong, non-locking screw hole, one (1) VA 3.5 mm screw hole, and 6, 8, 10, 12, or 14 LOQTEQ® 3.5 mm gliding locking-compression screw holes.

The subject device LOQTEQ® Cortical Screws have a standard cortical thread, 3.5 mm in diameter that tapers slightly at the tip. The heads of the screws are threaded to lock into the VA variable angle holes in the subject device plates. The screws are provided in overall lengths of 20 mm to 60 mm, in 2 mm increments.

The subject device LOQTEQ® Cancellous Screws have a standard cancellous thread, 4.0 mm thread diameter that tapers slightly at the tip. The heads of the screws are threaded to lock into the VA variable angle holes in the subject device plates. The screws are provided in overall lengths of 20 mm to 60 mm, in 2 mm increments.

The subject device plates and screws are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 and ISO 5832-3.

## PERFORMANCE DATA

Recognized standards used in the non-clinical performance testing included:

ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*;

ISO 5832-3 *Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy*;

ASTM F2182 *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance;*

ASTM F2052 *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment;*

ASTM F2213 *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment;*

ASTM F2119 *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants;*

ASTM F2182 *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance;*

ANSI/AAMI/ISO 17665-1 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*;

ANSI/AAMI/ISO TIR 17665-2 *Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1*; and

ASTM F543 *Standard Specification and Test Methods for Metallic Medical Bone Screws*.

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- referenced from the reference device K233008 was moist heat sterilization validation to a sterility assurance level of $10^{-6}$ by the overkill method according to ANSI/AAMI/ISO 17665-1, ANSI/AAMI/ISO TIR 17665-2; analysis showed that the subject devices do not create a new worst case for moist heat sterilization;
- referenced from the primary predicate device K211582 and the reference device K121495 was biocompatibility for the subject device materials;
- provided in this submission was testing of the subject device within the magnetic resonance environment according to ASTM F2182, ASTM F2052, ASTM F2213, ASTM F2119, and ASTM F2182;
- provided in this submission was mechanical testing of the subject device plate and screw constructs and mechanical testing of predicate device plate and screw constructs using a fracture gap model; and
- provided in this submission was mechanical testing according to ASTM F543.

No clinical data were included in this submission.

## EQUIVALENCE TO MARKETED DEVICES

The subject device and the primary predicate device K211582 have the same technological characteristics and use the same operating principles for bone fixation. The subject device and the primary predicate device include similar anatomic designs for placement on the proximal humerus, with screw holes to accommodate locking and non-locking screws. The subject device designs in lengths ranging from 84 mm to 255 mm with 3-16 holes, are similar in lengths (85 mm to 247 mm) to the plates cleared in K211582 and K041860.

The subject device plates incorporate multidirectional polyaxial or VA (variable angle) locking screw hole technology that is identical to that cleared in the reference device K230141.

The subject device LOQTEQ® cortical locking screws (3.5 mm diameter, 20-60 mm length) are substantially equivalent in design to screws cleared in the reference device K113652 (LOQTEQ® cortical locking screws 3.5 mm diameter, 10-90 mm length). The subject device LOQTEQ® cancellous locking screws are substantially equivalent to LOQTEQ® cancellous locking screws cleared in the reference device K121495.

The subject devices are compatible with aap 3.5 mm cortical screws previously cleared in K141949, and with 3.5 mm LOQTEQ® 3.5 mm cortical locking screws cleared in K113652. The subject device plates also are compatible with K Wires previously cleared in K131459.

The subject device plates, the plates cleared in the primary predicate device K211582, and the plates cleared in the reference devices K121495 and K230141 are manufactured from the identical titanium alloy material conforming to ASTM F136 and ISO 5832-3. Similarly, the subject device screws, and the screws cleared in the reference devices K121495 and K233008 are manufactured from the identical titanium alloy material conforming to ASTM F136 and ISO 5832-3, and are anodized using a process identical to that used for screws cleared in K211582.

All subject device final finished components are manufactured in the same facilities using identical materials and identical manufacturing processes as used for previously cleared aap components (K211582, K121495, K230141, and K233008). Similarly, the Class II device-specific accessories and Class I instruments are manufactured in the same facilities using identical materials and identical manufacturing processes as the Class I instruments and cleared Class II accessories in K211582 and K233008. Therefore, the subject devices are substantially equivalent to the primary predicate and reference devices (K211582, K121495, K230141, and K233008) with regard to biocompatibility.

The subject device includes components provided non-sterile in the same packaging as devices previously cleared in K230141, to be sterilized to a sterility assurance level (SAL) of 10-6 by the end user using the same sterilization method (moist heat) and parameters as devices previously cleared in K233008.
Sterilization validation for the subject device components assembled in trays is referenced from K233008. The moist heat sterilization validation referenced from K233008 was performed to a sterility assurance level of $10^{-6}$ by the overkill method according to ISO 17665-1 and ISO TS 17665-2. The referenced sterilization validation included a worst case kit and configuration based on design features that are the most challenging to the moist heat sterilization process, such as presence of lumen, geometry, and surface area. The subject device plates and screws do not create a new worst-case and do not introduce new design features that create a greater challenge to the sterilization process.

In support of substantial equivalence of the strength of the subject plates dynamic mechanical testing was performed using a fracture gap construct model. In support of substantial equivalence of the strength of the subject device screws mechanical testing was performed according to ASTM F543.

## CONCLUSION

The subject devices, the primary predicate device, and the reference devices have the same intended use and similar technological characteristics. They encompass a similar range of physical dimensions, are manufactured from the same materials, and are to be sterilized using identical methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.