March 3, 2021

AAP Implantate AG
% Kevin A. Thomas
Vice President and Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K210043
Trade/Device Name: LOQTEQ® Distal Lateral Femur Plate 4.5 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: January 6, 2021
Received: January 7, 2021

Dear Kevin A. 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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, M.P.H.
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*

K210043

Device Name

LOQTEQ® Distal Lateral Femur Plate 4.5 System

Indications for Use *(Describe)*

Buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures; fractures in normal or osteopenic bone; non-unions and malunions; and osteotomies of the femur

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.

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# 510(k) Summary

## K210043

## LOQTEQ® Distal Lateral Femur Plate 4.5 System

## *aap* Implantate AG

March 1, 2021

ADMINISTRATIVE INFORMATION


| | |
|---|---|
| Manufacturer Name | *aap* Implantate AG<br>Lorenzweg 5<br>12099 Berlin Germany<br>Telephone: +11 49 30 75019129<br>Fax: +11 49 30 75019111 |
| Official Contact | Agnieszka Mierzejewska, Chief Operating Officer (COO) |
| Representative/Consultant | Kevin A. Thomas, PhD<br>Floyd G. Larson, MS, MBA<br>PaxMed International, LLC<br>12264 El Camino Real, Suite 400<br>San Diego, CA 92130<br>Telephone: +1 858-792-1235<br>Fax: +1 858-792-1236<br>Email: kthomas@paxmed.com<br>flarson@paxmed.com |


DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Device Name | LOQTEQ® Distal Lateral Femur Plate 4.5 System |
| Common Name | Plate, Fixation, Bone |
| Regulation Number | 21 CFR 888.3030 |
| Regulation Name | Single/multiple component metallic bone fixation appliances and accessories |
| Regulatory Class | Class II |
| Product Code | HRS |
| Classification Panel | Orthopedic |
| Reviewing Division | Office of Orthopedic Devices (OHT6)<br>Division of Restorative, Repair and Trauma Devices (DHT6C)<br>Stereotaxic, Bone Growth Stimulators and Fracture Fixation Devices Team |

PREDICATE DEVICE INFORMATION

Primary Predicate
K121494, *aap* LOQTEQ Distal Lateral Femur Plate 4.5 System
Additional Predicate
K062564, Synthes LCP Distal Femur Plates
Reference Device
K153034, *aap* LOQTEQ® VA Radius Set 2.5

INDICATIONS FOR USE STATEMENT
Buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-articular condylar, periprosthetic fractures; fractures in normal or osteopenic bone; non-unions and malunions; and osteotomies of the femur

SUBJECT DEVICE DESCRIPTION
The subject device includes a total of 14 bones plates for internal fixation of the distal lateral femur. All LOQTEQ Distal Lateral Femur Plates 4.5 are available non-sterile.

The subject device is provided in anatomic designs in overall lengths of 153 mm, 207 mm, 243 mm, 279 mm, 314 mm, 350 mm, and 386 mm, for the left and right distal femur. The plates are provided with 4, 7, 9, 11, 13, 15, and 17 screw holes, respectively, in the shaft of the plate. Lengths of 153 mm, 207 mm, 243 mm, 279 mm, and 314 mm are identical to the plates previously cleared in K121494. Subject device plates in lengths of 350 mm and 386 mm are identical to the plates previously cleared in K121494, except for the length.

The subject device plates include screw holes designed to accommodate appropriately sized locking and non-locking cortical and periprosthetic bone screws, previously cleared in K121494 and K072411 and K-wires, previously cleared in K131459, presently marketed as part of the LOQTEQ Distal Lateral Femur Plate 4.5 System. The compatible screws are 4.5 mm in diameter. The subject device plates also are compatible with 2.0 mm diameter *aap* K-Wires.

PERFORMANCE DATA
Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility referenced from K121494 and K153034; validation of the recommended end-user moist heat sterilization cycle; and mechanical testing referenced from K121494. Clinical data were not submitted in this premarket notification.

EQUIVALENCE TO MARKETED DEVICES
The primary predicate device is the manufacture's own device K121494, *aap* LOQTEQ Distal Lateral Femur Plate 4.5 System. The additional predicate device is K062564, Synthes LCP Distal Femur Plates, Synthes (USA). The reference device is the manufacture's own device K153034, *aap* LOQTEQ® VA Radius Set 2.5, *aap* Implantate AG.

The subject device is substantially equivalent in indications and design principles to the predicate devices listed above. The subject device has similar Indications for Use Statements (IFUS) to those of devices previously cleared in K121494 and K062564. Differences between the subject device and primary predicate device K121494 include the statement "The aap LOQTEQ® Distal lateral Femur Plate 4.5 System includes plates for the left and right human femur. The plates accept 4.5 mm locking screws, 4.5 mm cortical screws and 4.5 mm periprosthetic screws." The statement was removed from the subject device IFUS because the statement describes the device rather than defining "..the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended" per 21 CFR §814.20(b)(3)(i). Differences between the subject device and the additional predicate device K062564 are limited to device trade or proprietary name. These differences do not impact the substantial equivalence because all IFUS express the same intended use for buttressing multifragmentary distal femur fractures including: supracondylar, intra-articular and extra-

articular condylar, periprosthetic fractures; fractures in normal or osteopenic bone; non-unions and malunions; and osteotomies of the femur.

The subject device, the primary predicate device K121494, and the additional predicate device K062564 have the same technological characteristics and use the same operating principles for bone fixation. Furthermore, the subject device, the primary predicate device, and the additional predicate device include similar anatomic designs for distal lateral placement on the femur, with screw holes to accommodate locking and non-locking screws. The subject device designs in lengths of 153 mm, 207 mm, 243 mm, 279 mm, and 314 mm, with 4, 7, 9, 11, and 13 holes, respectively, are identical to the plates cleared in K121494. Subject device lengths of 350 mm and 386 mm, with 15 and 17 holes, respectively, have identical design characteristics as plates cleared in K121494, and encompass a similar range of dimensions as K062564. These two new lengths do not create a new worst case for mechanical testing.

The subject device and the primary predicate device K121494 are manufactured from the identical titanium alloy material conforming to ASTM F136. All subject device final finished components are manufactured in the same facilities using identical materials and identical manufacturing processes as used for the previously cleared *aap* device components (K121494 and K153034). 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 II accessories and Class I instruments previously cleared in K121494 and K153034. Therefore, the subject devices are substantially equivalent to K121494 and K153034 regarding biocompatibility.

The subject device includes components provided non-sterile in the same packaging and are 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 K121494. The subject devices do not represent a new worst case for the sterilization validation.

In summary, non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility referenced from K121494 and K153034; validation of the recommended end-user moist heat sterilization cycle and mechanical testing referenced from K121494. Clinical data were not submitted in this premarket notification.

Any differences in the technological characteristics among the subject and predicate devices do not raise different questions of safety and effectiveness. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

CONCLUSION

The subject devices, the primary predicate device, and the additional predicate device 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.