October 18, 2021

aap Implantate AG
% Melissa Burbage
Sr. Regulatory Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K211582
Trade/Device Name: LOQTEQ® Proximal Humerus Plate 3.5 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: May 19, 2021
Received: May 21, 2021

Dear Melissa Burbage:

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)*

K211582

Device Name

LOQTEQ® Proximal Humerus Plate 3.5 System

Indications for Use *(Describe)*

The LOQTEQ® Proximal Humerus Plate 3.5 System is intended 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.

510(k) Summary

K211582

LOQTEQ® Proximal Humerus Plate 3.5 System

aap Implantate AG

October 15, 2021

ADMINISTRATIVE INFORMATION

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

DEVICE NAME AND CLASSIFICATION

Trade/Device Name	LOQTEQ® Proximal Humerus Plate 3.5 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) Division of Restorative, Repair and Trauma Devices (DHT6C) Stereotaxic, Bone Growth Stimulators and Fracture Fixation Devices Team

PREDICATE DEVICE INFORMATION

Primary Predicate
K121495, *aap* LOQTEQ® Proximal Humerus Plate 3.5 System
Additional Predicate
K041860, Synthes LCP Proximal Humerus Plate, Long

INDICATIONS FOR USE STATEMENT

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

SUBJECT DEVICE DESCRIPTION

The subject device includes a total of nine (9) bones plates for internal fixation of bone fragments, i.e., for treatment of bone fracture and other bone injuries. All LOQTEQ® Proximal Humerus Plate 3.5 are available non-sterile.

The subject device is provided in anatomic designs in overall lengths of 85 mm, 92 mm, 105 mm, 118 mm, 143 mm, 169 mm, 195 mm, 221 mm, and 247 mm. The plates are provided with 3, 4, 5, 6, 8, 10, 12, 14, and 16 holes, respectively, in plate. The lengths of 92 mm, 105 mm, 118 mm, 143 mm, 169 mm, and 195 mm are identical to the plates previously cleared in K121495. Subject device lengths of 85 mm, 221 mm, and 247 mm are identical to the plates previously cleared in K121495 except for the length and number of holes.

The subject device plates include screw holes designed to accommodate appropriately sized locking and non-locking cortical and periprosthetic bone screws, previously cleared in K121495, and K-wires cleared in K131459, presented marked as part of the LOQTEQ® Proximal Humerus Plate 3.5 System. The compatible screws are 3.5 mm or 3.8 mm in diameter. The subject device plates are also compatible with the 1.6 mm diameter *app* K-Wires.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include biocompatibility referenced from K121495; validation of the recommended end-user moist heat sterilization cycle according to 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*. An assessment of the biomechanical performance of the subject device to determine substantial equivalence was performed based on cross sectional analysis of the subject device as compared to the predicate device plates in submission K121495. Clinical data were not submitted in this premarket notification.

COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

The primary predicate device is the manufacture's own device K121495, *aap* LOQTEQ® Proximal Humerus Plate 3.5 System. The additional predicate device is K041860, Synthes LCP Proximal Humerus Plate, Long, Synthes (USA).

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 K121495 and K041860. Differences between the subject device and primary predicate device K121495 include the statement "The aap LOQTEQ®

Proximal Humerus Plate 3.5 System includes LOQTEQ® Proximal Humerus Plate 3.5 short and LOQTEQ® Proximal Humerus Plate 3.5 long. The plates accept 3.5 mm cortical locking screws and 3.5 mm cortical screws as well as 3.8 mm cancellous locking 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). The compatibility of the subject device plates and previously cleared screws is described in the Instructions for Use and Surgical Technique. Differences between the subject device and the additional predicate device K041860 are limited to the device trade or proprietary name. These differences do not impact the substantial equivalence because all IFUS express the same intended use for fractures and fracture dislocations, osteotomies, and nonunions of the proximal humerus, particularly in osteopenic bone.

The subject device, the primary predicate device K121495, and the additional predicate device K041860 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 placement on the proximal humerus, with screw holes to accommodate locking and non-locking screws. The subject device designs in lengths of 92 mm, 105 mm, 118 mm, 143 mm, 169 mm, and 195 mm with 4, 5, 6, 8,10, and 12 holes, respectively, are identical to the plates cleared in K121495. Subject device lengths of 85 mm, 221 mm, and 247 mm, with 3, 14 and 16 holes, respectively, have identical design characteristics as plates cleared in K121495, and encompass a similar range of dimensions as K041860 (secondary predicate). These two new lengths do not create a new worst case for mechanical testing.

The subject device and the primary predicate device K121495 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). 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 K121495. Therefore, the subject devices are substantially equivalent to K121495 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 K121495. The subject devices do not represent a new worst case for the sterilization validation.

Feature	**Subject Device** K211582 LOQTEQ Proximal Humerus Plates 3.5 aap lmplantate AG	**Primary Predicate Device** K121495 LOQTEQ Proximal Humerus Plates 3.5 aap lmplantate AG	**Additional Predicate Device** K041860 Synthes LCP Proximal Humerus Plates, Long Synthes USA
Product Code	HRS	HRS, HWC	KTW
Indications for Use	The LOQTEQ Proximal Humerus Plate 3.5 System is intended for fractures and fracture dislocations, osteotomies, and nonunions of the proximal humerus, particularly in osteopenic bone.	The aap LOQTEQ Proximal Humerus Plate 3.5 System includes LOQTEQ Proximal Humerus Plate 3.5 short and LOQTEQ Proximal Humerus Plate 3.5 long. The plates accept 3.5 mm cortical locking screws and 3.5 mm cortical	Synthes (USA) LCP Proximal Humerus Plate, long is indicated for fractures and fracture dislocations, osteotomies, and nonunions of the proximal humerus, particularly in osteopenic bone.

Feature	Subject Device K211582 LOQTEQ Proximal Humerus Plates 3.5 aap lmplantate AG	Primary Predicate Device K121495 LOQTEQ Proximal Humerus Plates 3.5 aap lmplantate AG	Additional Predicate Device K041860 Synthes LCP Proximal Humerus Plates, Long Synthes USA
		screws as well as 3.8 mm cancellous locking screws. The LOQTEQ Proximal Humerus Plate 3.5 System is intended for fractures and fracture dislocations, osteotomies, and nonunions of the proximal humerus, particularly in osteopenic bone.	
Reason for Predicate/Reference Device	Not applicable	Plate designs, including use with locking and non-locking screws; Compatible screws; Materials ASTM F136	Plate length, plate designs, including use with locking and non-locking screws; Reference devices for comparison mechanical testing:
Plate Materials	Ti-6Al-4V alloy, ASTM F136	Ti-6Al-4V alloy, ASTM F136	Ti-6Al-4VNb alloy or Stainless Steel 316L
Type of Holes	Gliding-holes (locking/compression) Round holes (locking only)	Gliding-holes (locking/compression) Round holes (locking only)	Gliding-holes (locking/compression) Round holes (locking only)
Plate Length	Short Plates 3 holes, 85 mm 4 holes, 92 mm 5 holes, 105 mm 6 holes 118 mm Long Plates 8 holes, 143 mm 10 holes, 169 mm 12 holes, 195 mm 14 holes, 221 mm 16 holes, 247 mm	Short Plates 4 holes, 92 mm 5 holes, 105 mm 6 holes 118 mm Long Plates 8 holes, 143 mm 10 holes, 169 mm 12 holes, 195 mm	Short Plates 3 holes, 90 mm 5 holes, 114 mm Long Plates 5 holes 142 mm 6 holes, 160 mm 8 holes, 196 mm 10 holes, 232 mm 12 holes, 268 mm
Head & Shaft Dimensions	Short Plates Head width: 23 mm Head thickness: 3.5 mm Shaft width: 12 mm Shaft thickness: 3.5 mm Long Plates Head width: 23 mm Head thickness: 3.5 mm Shaft width: 13 mm Shaft thickness: 4.5 mm	Short Plates Head width: 23 mm Head thickness: 3.5 mm Shaft width: 12 mm Shaft thickness: 3.5 mm Long Plates Head width: 23 mm Head thickness: 3.5 mm Shaft width: 13 mm Shaft thickness: 4.5 mm	Short Plates Head width: 20 mm Head thickness: 2.5 mm Shaft width: 12 mm Shaft thickness: 2.5 mm Long Plates Head width: 20 mm Head thickness: 3.0 mm Shaft width: 12 mm Shaft thickness: 3.7 mm
Surface Treatment	Polished	Polished	Type III anodization
Screw Diameters	*No new screws* Cancellous screws: 3.8 mm diameter, 28-60 mm length Cortical screws, self-tapping: 3.5 mm diameter, 18-38 mm length	Cancellous screws: 3.8 mm diameter, 28-60 mm length Cortical screws, self-tapping: 3.5 mm diameter, 18-38 mm length	Cancellous screws, fully threaded: 4.0 mm diameter, 10-60 mm length Cancellous screws, partially threaded: 4.0 mm diameter, 10-50 mm length Cortex screws: 3.5 mm diameter, 10-60 mm length 4.0 mm diameter, 10-60 mm length (SS material only) Locking screws (SS material and

Feature	Subject Device K211582 LOQTEQ Proximal Humerus Plates 3.5 aap lmplantate AG	Primary Predicate Device K121495 LOQTEQ Proximal Humerus Plates 3.5 aap lmplantate AG	Additional Predicate Device K041860 Synthes LCP Proximal Humerus Plates, Long Synthes USA
			Ti-6Al-4VNb alloy only): 3.5 mm diameter, 10-60 length
Screw Materials	Ti-6Al-4V alloy, ASTM F136	Ti-6Al-4V alloy, ASTM F136	TiCP, Ti6Al7Nb, Ti-6Al-4V alloy, SS 316L
Surface Treatment	Anodized Type III (locking cancellous screw green) Partially anodized Type III (locking compression screw) Anodized Type III (non-locking screws gold)	Anodized Type III (locking cancellous screw green) Partially anodized Type III (locking compression screw) Anodized Type III (non-locking screws gold)	Anodized Type III (all screws)
How Provided			
Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile and Provided sterile
Sterilization	Non-sterile: to be sterilized by moist heat	Non-sterile: to be sterilized by moist heat	Non-sterile: to be sterilized by moist heat Sterile: method not stated
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

In summary, non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility referenced from K121495; validation of the recommended end-user moist heat sterilization cycle according to 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.* An assessment of the biomechanical performance of the subject device to determine substantial equivalence was performed based on cross sectional analysis of the subject device as compared to the predicate device plates in submission K121495. 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.