March 17, 2023

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

Re: K230141
Trade/Device Name: LOQTEQ® VA Elbow Plates 2.7/3.5 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: November 18, 2022
Received: January 18, 2023

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 -S

Shumaya Ali, MPH
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)*
K230141

Device Name

LOQTEQ® VA Elbow Plates 2.7/3.5

Indications for Use *(Describe)*

The LOQTEQ® VA Elbow Plates 2.7/3.5 includes the LOQTEQ® VA Distal Medial Humerus Plate 2.7/3.5, LOQTEQ® VA Distal Dorsolateral Humerus Plate 2.7/3.5, LOQTEQ® VA Distal Lateral Humerus Plate 2.7/3.5 and LOQTEQ® VA Olecranon Plate 2.7/3.5.

LOQTEQ® VA Distal Medial Humerus Plate 2.7/3.5, LOQTEQ® VA Distal Dorsolateral Humerus Plate 2.7/3.5, LOQTEQ® VA Distal Lateral Humerus Plate 2.7/3.5 are indicated for:
• Intra-articular fractures of the distal humerus
• Supracondylar fractures of the distal humerus
• Osteotomies, and non-unions of the distal humerus

LOQTEQ® VA Olecranon Plate 2.7/3.5 is indicated for:
• Fixation of fractures, osteotomies and non-unions of the olecranon, 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.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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510(k) Summary

K230141

LOQTEQ® VA Elbow Plates 2.7/3.5

aap Implantate AG

March 17, 2022

ADMINISTRATIVE INFORMATION

Manufacturer Name	*aap* Implantate AG Lorenzweg 5 12099 Berlin Germany Telephone: +49 30 750 19 129 Fax: +49 30 750 19 111
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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® VA Elbow Plates 2.7/3.5
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 Device
K132787, aap LOQTEQ® Elbow System, aap Implantate AG

Additional Predicate Devices
K140607, aap LOQTEQ® Olecranon Plate, aap Implantate AG
K161696, aap LOQTEQ® Distal Lateral Humerus Plate 2.7/3.5, aap Implantate AG
K120717, Synthes Variable Angle LCP Elbow System, Synthes

INDICATIONS FOR USE STATEMENT

The LOQTEQ® VA Elbow Plates 2.7/3.5 includes the LOQTEQ® VA Distal Medial Humerus Plate 2.7/3.5, LOQTEQ® VA Distal Dorsolateral Humerus Plate 2.7/3.5, LOQTEQ® VA Distal Lateral Humerus Plate 2.7/3.5 and LOQTEQ® VA Olecranon Plate 2.7/3.5.

LOQTEQ® VA Distal Medial Humerus Plate 2.7/3.5, LOQTEQ® VA Distal Dorsolateral Humerus Plate 2.7/3.5, LOQTEQ® VA Distal Lateral Humerus Plate 2.7/3.5 are indicated for:
• Intra-articular fractures of the distal humerus
• Supracondylar fractures of the distal humerus
• Osteotomies, and non-unions of the distal humerus

LOQTEQ® VA Olecranon Plate 2.7/3.5 is indicated for:
• Fixation of fractures, osteotomies and non-unions of the olecranon, particularly in osteopenic bone

SUBJECT DEVICE DESCRIPTION

The components of the LOQTEQ VA Elbow Plates 2.7/3.5 are trauma implants, bone plates and screws, which are implanted into the human body to achieve an internal fixation of bone fragments, typically after fractures or other bone injuries (e.g., joint reconstruction). LOQTEQ plates function according to the fixateur interne principle, i.e., they incorporate an angular stable plate-screw connection as a result of screwing threaded screw heads into threaded plate holes. Conventional bone screws can be used in all plate holes and allow for off-axis angulation up to 15° inside threaded plate holes. After fracture healing, the implants (plates and screws) are to be removed.

The shape of the bone plates is adapted to the anatomy of and the biomechanical stress on the distal humerus and the olecranon (ulna), respectively.

The LOQTEQ VA Elbow Plates 2.7/3.5 consists of the LOQTEQ VA Distal Dorsolateral Humerus Plate, LOQTEQ VA Distal Lateral Humerus Plate, LOQTEQ VA Distal Medial Humerus Plate and the LOQTEQ VA Olecranon Plate 2.7/3.5.

PERFORMANCE DATA

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence to from predicate devices K132787, K140607, and K161696 included biocompatibility and 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*. Mechanical testing against the predicate device K120717 was completed. Clinical data were not submitted in this premarket notification.

EQUIVALENCE TO MARKETED DEVICES

The subject device, predicate devices K132787, K140607, K161696, and K120717 have the same technological characteristics and use the same operating principles for bone fixation. The plate

design and dimensions are the same as predicate devices K132787, K140607, and K161696. Slight modifications have been made to the plates to accommodate the variable angle feature that is similar to the predicate device K120717.

The subject devices are compatible with *aap* locking and non-locking screws previously cleared with predicate devices K132787, K140607, and K161696.

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.