August 1, 2019

aap Implantate AG
Annesha Lahiri
Head of Regulatory Affairs
Lorenzweg 5
Berlin, D-12099 De

Re: K182818
Trade/Device Name: LOQTEQ VA Calcaneus 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: June 28, 2019
Received: July 2, 2019

Dear Annesha Lahiri:

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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182818

Device Name
LOQTEQ® VA Calcaneus Plate 3.5

Indications for Use *(Describe)*

For fractures and osteotomies of the calcaneus, including, but not limited to

-extra-articular, intra-articular
-joint depression
-tongue type
-severely comminuted fractures

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) Traditional Premarket Notification
aap LOQTEQ® VA Calcaneus Plate 3.5

510(k) Summary
LOQTEQ® VA Calcaneus Plate 3.5

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Submitter: *aap* Implantate AG

Address: Lorenzweg 5
D-12099 Berlin, Germany

Telephone: +49-30-750-19 -193
Telefax: +49-30-750-19 –111
Contact: Dr. Annesha Lahiri
Date Prepared: 2019-07-19

Name of Device and Name/Address of Sponsor

Trade Name: LOQTEQ® VA Calcaneus Plate 3.5
Common Name: Plate, Fixation, Bone; Screw, Fixation, Bone
Classification: Class II per 21 CFR 888.3030, 21 CFR 888.3040
Device: Orthopedics
Product Code: HRS and HWC

Predicate Devices

PREDICATE 510(K) NUMBER	PREDICATE DEVICE NAME	PREDIVATE DEVICE MANUFACTURER
K991407 - Primary	Synthes Locking Calcaneal Plate	Synthes
K072411	aap Bone Plate and Screw Implants	aap Implantate AG

510(k) Traditional Premarket Notification
***aap* LOQTEQ® VA Calcaneus Plate 3.5**

Intended Use

The plate and screw implants of the system LOQTEQ® VA Calcaneus Plate 3.5 are intended for temporary fixation, correction or stabilization of the calcaneus. Implants are intended for single use on human bone.

Indications for Use

For fractures and osteotomies of the calcaneus, including, but not limited to

- extra-articular, intra-articular
- joint depression
- tongue type
- severely comminuted fractures

Product Description

The **LOQTEQ® VA Calcaneus Plate 3.5** is an anatomical, polyaxial angular stable, asymmetrical titanium plate (L/R version) for the treatment of calcaneus fractures. The shape of the plate is adapted to the lateral, anatomical shape of the calcaneus.

The polyaxial, angle-stable plate-screw-connection (VA technology) allows up to 15° angulating of the screws. Thus, the screws can be placed under the posterior articular facet into the sustentaculum tali, ensuring a stable supply of the fracture.

Substantial Equivalence

The LOQTEQ® VA Calcaneus Plate 3.5 has comparable intended use and identical indications for use as the predicate. The technological characteristics, functionality (both being internal fixatures) and materials (TiCP) are identical whereas dimensions and mechanical properties are comparable.

The cancellous screws which are a part of this submission have been compared to predicate screw approved in the K072411. Bench testing of the subject screws showed that these functioned similar to the predicates.

Hence no questions on the safety and the efficacy of the bone plate and screw system are raised.

510(k) Traditional Premarket Notification
***aap* LOQTEQ® VA Calcaneus Plate 3.5**

Performance Testing

In order to evaluate the mechanical safety of the LOQTEQ® VA Calcaneus Plate 3.5, customized static and dynamic 3-point-bending tests of bone plates according to ASTM F2193 and ASTM F382 was performed. Mechanical testing for the subject screws according to ASTM F543 was performed. In all instances, the LOQTEQ® VA Calcaneus Plate 3.5 plate and screw system functioned as intended and had similar results as the predicate devices.

Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, the LOQTEQ® VA Calcaneus Plate 3.5 has been shown to be substantially equivalent to the predicate devices and does not present any different issues of safety or effectiveness. The results from the bench testing demonstrate that the device performs as good or better than the predicate devices.