June 19, 2019

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

Re: K182785
Trade/Device Name: LOQTEQ VA Foot Plates 2.5
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: April 18, 2019
Received: April 29, 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182785

Device Name
LOQTEQ VA Foot Plates 2.5

Indications for Use *(Describe)*

LOQTEQ® VA Plantar Fusion Plate 2.5, TMT 1:
• plantar stabilization of arthrodesis/fusions of the first metatarsal joint (Lapidus procedure)

LOQTEQ® VA L-Fusion Plate 2.5:
• LisFranc Arthrodesis and/or Stabilization
• 2nd Tarsometatarsal (TMT) Fusions

LOQTEQ® VA Straight Fusion Plate 2.5:
• LisFranc Arthrodesis and/or Stabilization
• 3rd Tarsometatarsal (TMT) Fusions

LOQTEQ® VA Osteotomy Plate 2.5:
First metatarsal osteotomies for hallux valgus correction including:
• Opening base wedge osteotomy
• Closing base wedge osteotomy
• Proximal Chevron osteotomy

LOQTEQ® VA MTP Fusion Plate 2.5:
Arthrodesis of the first metatarsophalangeal joint (MTP) including:
• Primary MTP Fusion due to hallux rigidus and/or hallux valgus

LOQTEQ® VA MTP Revision Plate 2.5:
Arthrodesis of the first metatarsophalangeal joint (MTP) including:
• Revision MTP Fusion
• Revision of failed first MTP Arthroplasty implant

LOQTEQ® VA Metatarsal Straight Plate 2.5/LOQTEQ® VA Metatarsal L-Plate 2.5/LOQTEQ® VA Metatarsal T-Plate 2.5
• Metatarsal or metacarpal fractures and osteotomies
• Phalanges fractures and osteotomies

LOQTEQ® VA X-Plate 2.5:
• fixation of factures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, including the foot

LOQTEQ® VA Hook Plate 2.5:
• internal bone fixation for bone fractures of the 5th metatarsal of the foot

LOQTEQ® VA Plantar Fusion Plate 3.5, TMT 1:
• plantar stabilization of arthrodesis/fusions of the first metatarsal joint (Lapidus procedure)

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.

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510(k) Traditional Premarket Notification
***aap* LOQTEQ® VA Foot Plates 2.5**

VOL_007_510(k) Summary

510(k) Summary
LOQTEQ® VA Foot Plates 2.5

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

Submitter: *aap* Implantate AG

Address: Lorenzweg 5
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Contact: Dr. Annesha Lahiri

Date Prepared: 2018-09-28

Name of Device and Name/Address of Sponsor

Trade Name: aap LOQTEQ® VA Foot Plates 2.5
Common Name: LOQTEQ® VA Foot Plates 2.5
Classification: Class II per 21 CFR 888.3030
Device: Orthopedics
Product Code: HRS and HWC

Predicate Devices

510(K) Number	Trade Name	Manufacturer
K150520	DARCO® Locking Bone Plate System	Wright Medical
K121651	ORTHOLOC 3Di Midfoot/Flatfoot System	Wright Medical
K120359	ORTHOLOCTM 3Di Hallux System-Primary Predicate	Wright Medical
K090692	ORTHOLOC® 2.0/2.4 Plate & ORTHOLOC®2 .0/2 .4 Screw	Wright Medical

K071264	Synthes (USA) 2.4/2.7mm Locking Foot Module	Synthes
K150456	Arthrex Plates, Screws, and Staples	Arthrex

Table 1: List of predicate devices

Intended Use:

The system LOQTEQ® VA Foot Plates 2.5 is intended for use in stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of bones of the feet. Implants are intended for single use on adult human bone.

Indications of Use:

LOQTEQ® VA Plantar Fusion Plate 2.5, TMT 1:

- plantar stabilization of arthrodesis/fusions of the first metatarsal joint (Lapidus procedure)

LOQTEQ® VA L-Fusion Plate 2.5:

- LisFranc Arthrodesis and/or Stabilization
- 2nd Tarsometatarsal (TMT) Fusions

LOQTEQ® VA Straight Fusion Plate 2.5:

- LisFranc Arthrodesis and/or Stabilization
- 3rd Tarsometatarsal (TMT) Fusions

LOQTEQ® VA Osteotomy Plate 2.5:

First metatarsal osteotomies for hallux valgus correction including:

- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Proximal Chevron osteotomy

LOQTEQ® VA MTP Fusion Plate 2.5:

Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux rigidus and/or hallux valgus

LOQTEQ® VA MTP Revision Plate 2.5:

Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

LOQTEQ® VA Metatarsal Straight Plate 2.5/LOQTEQ® VA Metatarsal L-Plate 2.5/

LOQTEQ® VA Metatarsal T-Plate 2.5 :

- Metatarsal or metacarpal fractures and osteotomies
- Phalanges fractures and osteotomies

LOQTEQ® VA X-Plate 2.5:

- fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, including the foot

LOQTEQ® VA Hook Plate 2.5:

- internal bone fixation for bone fractures of the 5th metatarsal of the foot

LOQTEQ® VA Plantar Fusion Plate 3.5, TMT 1:

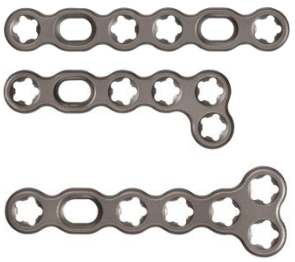
- plantar stabilization of arthrodesis/fusions of the first metatarsal joint (Lapidus procedure)

Product Description

The LOQTEQ® VA Foot Plates 2.5 includes invasive products for the implantation on bones of the foot. The implants consist of a titanium-aluminum-vanadium alloy (TiAl6V4) and have different kind of holes that can be used for fixation with polyaxial angular stable locking screws or standard cortical screws. The DC-hole can be used for dynamic compression with a lag screw. As the case may be, the plates can be placed with a K-wire to fix the plate temporarily before the screws are tightened. Table 1 shows the products that are included in the LOQTEQ® VA Foot Plates 2.5.

Product name	**Article number**	**Width** [mm]	**Thickness** [mm]	**Length** [mm]	**Image**
LOQTEQ® VA Plantar Fusion Plate 2.5, TMT 1	PF 2511-04-2	9.6	2	34.5	
LOQTEQ® VA Plantar Fusion Plate 3.5, TMT 1	PF 3511-04-2	11	2	38	
LOQTEQ® VA L-Fusion Plate	PF 2513-05-2	7.5	1.7	37.2	
LOQTEQ® VA Straight Fusion Plate 2.5	PF 2515-04-2	7.2	1.6	34.7	

510(k) Traditional Premarket Notification
***aap* LOQTEQ® VA Foot Plates 2.5**

Product name	Article number	Width [mm]	Thickness [mm]	Length [mm]	Image
LOQTEQ® VA X-Plate 2.5	PF 2544-0X-2	15.7 – 19.9	1.6	24.6 – 32.6	
LOQTEQ® VA Metatarsal Straight Plate 2.5 LOQTEQ® VA Metatarsal L-Plate 2.5 LOQTEQ® VA Metatarsal T-Plate 2.5	I: PF 2540-0X-2 L: PF 2541-0X-2 PF 2542-0X-2 T: PF 2543-0X-2	I: 6 L: 11 T: 11.8	I, L, T: 1.6	I: 27 - 51 L: 26 - 32 T: 30.5 – 42.5	
LOQTEQ® VA Hook Plate 2.5	PF 2545-06-2 PF 2545-07-2 PF 2545-08-2	7	1.7	43	
LOQTEQ® VA Osteotomy Plate 2.5	PF 253X-06-2	12	1.6	30 - 35	
LOQTEQ® VA MTP Fusion Plate 2.5	PF 252X-06-2	15.2	1.8	42 - 47	
LOQTEQ® VA MTP Revision Plate 2.5	PF 252X-09-2	15.5	2.2	60	
LOQTEQ® VA Cortical Screw 2.5, self-tapping	SK 2530-XX-2	n.a.	n.a.	08 - 40	
Cortical Screw 2.5, self-tapping	SK 2512-XX-2	n.a.	n.a.	08 - 40	

Product name	Article number	Width [mm]	Thickness [mm]	Length [mm]	Image
LOQTEQ® Cortical Screw 3.5, small head, self-tapping	SK 3526-XX-2	n.a.	n.a.	10 - 40	
Cortical Screw 3.5, self-tapping	SK 3514-XX-2	n.a.	n.a.	10 - 40	

Table 2: Description of system components

LOQTEQ® VA MTP Fusion Plate 2.5 & LOQTEQ® VA MTP Revision Plate 2.5

The LOQTEQ® VA MTP fusion plates consist of a MTP Fusion and MTP Revision plate. The MTP Fusion plate is available in two different lengths, while the MTP Revision plate is available in one length. Both kinds of plates can be obtained in right or left directed variant. The plates have polyaxial locking screw holes. These holes can be used for LOQTEQ® VA Cortical screws 2.5 mm. As an alternative, the polyaxial round holes can also be used with conventional non-locking 2.5 mm cortical screws (small head). The shape of the osteosynthesis plates fits to the anatomical condition of the metatarsal phalanges joint of the first metatarsal bone. Additionally, all plates have a (Revision plate has two) DC hole for compression in conjunction with conventional non-locking 2.5 mm cortical screws (small head). The plates have also one K-wire hole for the temporary fixation and positioning during the surgery.

LOQTEQ® VA Straight Fusion Plate 2.5 & LOQTEQ® VA L-Fusion Plate 2.5

These LOQTEQ® VA - fusion plates, consists of a straight and a L-form plate in one length. The L-plate is available in a left and in a right variant. The plates have polyaxial locking screw holes. These holes can be used for LOQTEQ® VA Cortical screws 2.5 mm. Alternatively, the polyaxial round holes can also be used with conventional non-locking 2.5 mm cortical screws (small head). Furthermore, all plates have a (Revision plate has two) DC hole for compression in conjunction with conventional non-locking 2.5 mm cortical screws (small head). The shape of the osteosynthesis plate fits to the anatomy of the second and third tarsometatarsal joint.

LOQTEQ® VA Hook Plate 2.5

The LOQTEQ® VA Hook plate is available in three different lengths and it has polyaxial locking screw holes, which can be used for LOQTEQ® VA Cortical screws 2.5 mm. As an alternative, the polyaxial round holes can also be used with conventional non-locking 2.5 mm cortical screws (small head). In addition, the plate has a DC hole for compression in conjunction with conventional non-locking 2.5 mm cortical screws (small head). The shape of the osteosynthesis plate fits to the anatomy of the fifth metatarsal bone.

LOQTEQ® VA Metatarsal Plates 2.5

The LOQTEQ® VA Metatarsal plates, consist of a straight L- form and T-form plate and are available in different lengths. The plates have polyaxial locking screw holes, which can be used for LOQTEQ® VA Cortical screws 2.5 mm. On the other hand, the polyaxial round holes can also be used with conventional non-locking 2.5 mm cortical screws (small head). Moreover, all plates have a (Straight plate has two) DC hole for compression in conjunction with conventional non-locking 2.5 mm cortical screws (small head). The shape of the osteosynthesis plates fits to the anatomy of the metatarsal of the fore and midfoot.

LOQTEQ® VA Osteotomy Plate 2.5

The LOQTEQ® VA Osteotomy Plate 2.5 is available in two different lengths. The plate has polyaxial locking screw holes, which can be used for LOQTEQ® VA Cortical screws 2.5 mm. As an alternative, the polyaxial round holes can also be used with conventional non-locking 2.5 mm cortical screws (small head). Additionally, the plate has a DC hole for compression in conjunction with conventional non-locking 2.5 mm cortical screws (small head). The shape of the osteosynthesis plate fits to the anatomy of the first metatarsal bone.

LOQTEQ® VA Plantar Fusion Plate 2.5 / LOQTEQ® VA Plantar Fusion Plate 3.5

The plantar LOQTEQ® VA Fusion Plate 2.5/3.5, TMT1 have two polyaxial locking screw holes which can be used for LOQTEQ® VA Cortical screws 2.5 mm or 3.5 mm, respectively. Alternatively, the polyaxial round holes can also be used with conventional non-locking 2.5 mm or 3.5 mm cortical screws (small head). Also, the plates have two oblong holes in conjunction with conventional non-locking 2.5 mm or 3.5 mm cortical screws (small head). The shape of the osteosynthesis plate fits to the anatomy of the first tarsometatarsal joint.

LOQTEQ® VA X-Plate 2.5

The LOQTEQ® VA X-Plate 2.5 is available in different sizes: small, medium and large. The plate has polyaxial locking screw holes, which can be used for LOQTEQ® VA Cortical screws 2.5 mm. Otherwise, the polyaxial round holes can also be used with conventional non-locking 2.5 mm cortical screws (small head). Due to its unique shape, the X-Plate can be used at different bones of the foot e.g. for fractures of the midfoot. Furthermore, all plates have two K-wire holes for temporary fixation of the plate during the surgery.

Substantial Equivalence

The LOQTEQ® VA Foot Plates 2.5 has comparable intended use and indications for use as the predicate devices. The device has

- comparable technological characteristics,
- identical indications for use,
- identical functionality,
- comparable materials

- comparable dimensions of components
- comparable mechanical properties (ensured by benchmark tests showing substantial equivalence – provided in this submission)

Thus, the device is substantially equivalent to its predicates

Performance Testing

Bench testing was conducted to determine the substantial equivalence to the predicates. In all instances, the LOQTEQ® VA Foot Plates 2.5 functioned as intended and had similar results as the predicate devices.

Performance Testing for the Plates

In order to evaluate the mechanical safety of the LOQTEQ® VA Foot Plates 2.5, Static and Dynamic 4-point-bending tests of bone plates according to ASTM F 382-14 have been performed. Test results (static and dynamic) were compared to the well clinically proven and equivalent benchmark products. The result of the static 4 point bending test has been used as basis for the dynamic tests. Testing was performed by an independent, certified and accredited test laboratory (MDD 93/42/EEC, ISO 17025): Questmed GmbH.
The non-clinical data demonstrated that the device performs comparably to the predicates device for the same intended use.

Performance testing for the screws –

Some screws that are a part of this submission have been already cleared in

1. K153034
2. K123875
3. K113652
4. K141949

The current submission includes some additional screw lengths which have bene tested in accordance with ASTM F543-13 -

- SK 2512-08-2: Cortical Screw 2.5, small head T8, self-tapping, Length 8mm
- SK 2530-08-2: LOQTEQ® VA Cortical Screw 2.5, T8, Length 8mm
- SK 2530-36-2: LOQTEQ® VA Cortical Screw 2.5, T8, Length 36mm
- SK 2530-38-2: LOQTEQ® VA Cortical Screw 2.5, T8, Length 38mm
- SK 2530-40-2: LOQTEQ® VA Cortical Screw 2.5, T8, Length 40mm
- SK 3526-10-2: LOQTEQ® Cortical Screw 3.5, small head, self-tapping, Length 10 mm

These screws were tested for Maximum Torque, Breaking Angle, Insertion Torque according to ASTM F543-13 and in all cases, the subject screws can be stated as safe and fit for use without raising any question on the safety and effectiveness of the device.

Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to the predicates, the LOQTEQ® VA Foot Plates 2.5 has been shown to be substantially equivalent to the predicate devices identified in this submission 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.