DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 22, 2016

aap Implantate AG
Reni Schaller
Manager Regulatory Affairs
Lorenzweg 5
Berlin, D-12099
Germany

Re: K161747
Trade/Device Name: LOQTEQ® VA Distal Tibia Plate System: LOQTEQ® VA Distal Medial Tibia Plate 3.5; LOQTEQ® VA Distal Anterolateral Tibia Plate 3.5; LOQTEQ® VA Distal Fibula Plate 2.7/3.5
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: October 17, 2016
Received: October 18, 2016

Dear Reni Schaller:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161747

Device Name
LOQTEQ® VA Distal Tibia Plate System
LOQTEQ® VA Distal Medial Tibia Plate 3.5; LOQTEQ® VA Distal Anterolateral Tibia Plate 3.5; LOQTEQ® VA Distal Fibula Plate 2.7/3.5

Indications for Use *(Describe)*

LOQTEQ® VA Distal Medial Tibia Plate 3.5
• Fixation of complex intra- and extra-articular fractures of the distal tibia; osteotomies of the distal tibia

LOQTEQ® VA Distal Anterolateral Tibia Plate 3.5
• fractures, osteotomies, and non-unions of the distal tibia, especially in osteopenic bone

LOQTEQ® VA Distal Fibula Plate 2.7/3.5
• fractures, osteotomies, and non-unions of the distal fibula, especially 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.

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5. 510(k) Summary

(as required by section 807.92)

(1)

Sponsor: ***aap* Implantate AG**
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D-12099 Berlin, Germany

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Date November/08/2016

(2)

Trade Name: LOQTEQ® VA Distal Tibia Plate System

- LOQTEQ® VA Distal Anterolateral Tibia Plate 3.5
- LOQTEQ® VA Distal Medial Tibia Plate 3.5
- LOQTEQ® VA Distal Fibula Plate 2.7/3.5

Common Name: Distal Tibia / Fibula Plates and Screws

Classification Name and Reference: 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories – Class II
21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener – Class II

Device Product Code and Panel Code: Orthopedics/87/HRS
Orthopedics/87/HWC

(3)

Predicate devices aap LOQTEQ 1/3 Tubular Plate 3.5 under the premarket notification **K113652**
Synthes (USA): LCP Distal Tibia Plates under the premarket notification **K013248**
Synthes (USA): 2.7 mm/3.5 mm LCP Anterolateral Distal Tibia Plates under the premarket notification **K092812**

(4)

Device Description: The aap LOQTEQ® VA Distal Tibia Plate System consists of bone plates and bone screws, to be implanted by a surgeon in order to achieve an internal fixation of bone fragments typically after fractures, osteotomies or non-unions.
The system includes anatomically preformed and angle-stable small fragment plates, which are available as right and left versions as well as in different lengths. The geometrical shape of those plates is based on the anatomy and biomechanical stress of the distal tibia/distal fibula. A flat plate design, smooth transition of cross sections, chamfers and roundings preserve soft tissue irritation. The tapered tip of those shafts enable a minimal invasive surgery. For a minimization of the contact between bone (tibia) and plate, all holes of the shaft zone are tunneled and the bottom of the plates is structured.
All plate holes, with exception of the oblong hole, are compatible with unidirectional locking screws as well as cortical screws. The use of locking screws is state of the art and particularly important in osteoporotic bones or for stabilizing comminuted fractures. The

elongated hole can be used to adjust the height as well as the initial fixation of the plate. The use as a conventional bone plate and screw osteosynthesis is also possible with standard cortical screws.

The System incorporates:

- LOQTEQ® VA Distal Anterolateral Tibia Plate 3.5, right/left
- LOQTEQ® VA Distal Medial Tibia Plate 3.5, right/left
- LOQTEQ® VA Distal Fibula Plate 2.7/3.5, right/left
- LOQTEQ® Cortical Screw 3.5, small head, T15, self-tapping
- Cortical Screw 2.5, small head, T8, self-tapping
- LOQTEQ® Cortical Screw 2.7, small head, T8, self-tapping
- Cortical Screw 3.5, T15, self-tapping
- LOQTEQ® Cortical Screw 3.5, T15, self-tapping
- LOQTEQ® Cortical Screw 3.5, small head, T15, self-tapping

Material: All Implants are made of: Ti6Al4V (ASTM F136 or ISO 5832-3)

Surface: The surface of the plates is generated by an automatic slide finishing, the so-called "KeramoFinish". Those surfaces correspond to polished surfaces. The surface of the LOQTEQ® Cortical Screws 3.5 are slightly polished and anodised. The surface of the Cortical Screws 3.5 and Cancellous Screws 4.0 are fine blasted and anodised as well.

(5)

Indications:

LOQTEQ® VA Distal Medial Tibia Plate 3.5:
Fixation of complex intra- and extra-articular fractures of the distal tibia; osteotomies of the distal tibia

LOQTEQ® VA Distal Anterolateral Tibia Plate 3.5:
Fractures, osteotomies, and non-unions of the distal tibia, especially in osteopenic bone

LOQTEQ® VA Distal Fibula Plate 2.7/3.5:
Fractures, osteotomies, and non-unions of the distal fibula, especially in osteopenic bone

(6a)

Technological characteristics Comparison

The LOQTEQ® VA Tibia Plate System and the legally marketed predicated devices have similar **indications**, **dimensions**, **geometry** and **materials**.

The LOQTEQ® VA Tibia Plate System is technologically substantially equivalent to the predicate devices according to the Decision-Making Process for 510(k)s:

1. Predicate device is legally marketed
2. The devices have the identical intended use
3. The devices have the similar technological characteristics

All characteristics which are known and are relevant for the safety for both devices are described and assessed mainly:

1.Indication for use statement: identical
2. Functionality: identical
3. Components, Materials, Dimensions of components: comparable
4. Mechanical properties (ensured by benchmark tests) at least comparable

Documentation including mechanical testing to show the substantial equivalence has been provided with this submission.

(6b)

Performance Data (Non-Clinical and/or Clinical):

Non-clinical tests have been performed and show the substantial equivalence of the device.
Clinical data and conclusions were not needed for this device.

Summary of Non-clinical tests:
Type of tests:
"Mechanical Safety of aap Implantate AG – LOQTEQ® VA Distal Fibula Plate 2.7/3.5, Static and Dynamic 4-point-bending test of bone plates according to ASTM F 382-14"

"Mechanical Safety of aap Implantate AG – LOQTEQ® VA Distal Anterolateral Tibia Plate 3.5 system, implant fatigue test with instable fracture gap model and progressive loadings"

"Mechanical Safety of aap Implantate AG – LOQTEQ® VA Distal Medial Tibia Plate 3.5 system, implant fatigue test with instable fracture gap model and progressive loadings"

"Biocompatibility of Implants and Instruments of aap LOQTEQ® VA Tibia Plate System"

Assessment of test results:
Substantial equivalence with respect to the mechanical performance of the aap system could be stated due to the test results gained.

The implants have successfully passed the tests and have hereby been proven to be mechanically as good as or better than the predicate devices.
Clinical Data were not needed for these devices to show substantial equivalence.

The LOQTEQ® VA Distal Tibia Plate System has passed all defined criteria, has performed as well or better than the predicate device and are therefore considered substantially equivalent to the cleared predicate device.