DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 4, 2016

AAP Implantate Ag
Reni Schaller
Manager Regulatory Affairs
Lorenzweg 5
Berlin, D-12099
Germany

Re: K161703
Trade/Device Name: LOQTEQ Distal Fibula Plate 3.5, Cancellous Screw 4.0, Washer
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, HTN
Dated: September 19, 2016
Received: September 20, 2016

Dear Ms. 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)*
K161703

Device Name

LOQTEQ® Distal Fibula Plate 3.5, Cancellous Screw 4.0, Washer

Indications for Use *(Describe)*

Fractures, osteotomies and non-unions of the distal fibula, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

(as required by section 807.92)

(1)

Sponsor: ***aap* Implantate AG**
Lorenzweg 5
D-12099 Berlin, Germany

Company Contact: Reni Schaller
Phone:+49-30-750-19 - 193
Fax: +49-30-750-19 – 111
Email: r.schaller@aap.de

Date October/27/2016

(2)

Trade Name: LOQTEQ® Distal Fibula Plate 3.5
Cancellous Screw 4.0
Washer

Common Name: Distal Fibula Plate and Screw, Cancellous Screw, Washer

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 & Panel Code: Orthopedics/87/HRS
Orthopedics/87/HWC
Orthopedics/87/HTN

(3)

Predicate devices
→ LOQTEQ® 1/3 Tubular Plate 3.5 under the premarket notification K113652 (LOQTEQ® Small Fragment Set)
→Cancellous Screw 4.0 under the premarket notification K072411
→Washer under the premarket notification K990776

(4)

Device Description:
The aap Plate and Screw System LOQTEQ® Distal Fibula Plates consists of bone plates and bone screws, to be implanted by a surgeon in order to achieve a repositioning of fragments and an internal fixation of the bone after fractures, osteotomies or non-unions. By using locking screws the plate screw system guarantees an additional mechanical fixation and enables the application for osteopenic bones.
The Distal Fibula Plate System 3.5 is part of the LOQTEQ® anatomic plate system. The anatomically preformed plates are available as right and left versions and in different lengths.
The tapered end of the plate enables tissue-conserving, submuscular insertion.
The 1.8 mm thin anatomic LOQTEQ® Distal Fibula Plate 3.5 prevents skin and soft tissue irritation.
All plate holes, with the exception of the oblong hole, are compatible with unidirectional locking screws as well as cortical screws (gold). The use of locking screws is state of the art and is 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 partially threaded Cancellous Screw dia 4.0 engages the remote bone fragment and slides through the bone fragment near the screw

	head. Thus, partially threaded screws enable interfragmentary compression. Washers in conjunction with aap screws are used to fixate small bone fragments. The aap Plate and Screw System LOQTEQ® Distal Fibula Plates 3.5 incorporates: • LOQTEQ® Distal Fibula Plate 3.5, right and left • LOQTEQ® Cortical Screw 3.5, small head, T15, self-tapping • Cortical Screw 3.5, T15, self-tapping • Cancellous Screw 4.0, small head, T15 • Washer**,** l-Ø4.4, A-Ø8.0 • Set of Instruments LOQTEQ® Distal Fibula Plates 3.5
Material:	All implants are made of Ti6Al4V (according ISO 5832-3 or ASTM F136)
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 are slightly polished and anodised. The surface of the Cortical Screws are fine blasted and anodised as well.
(5) **Indications:**	Fractures, osteotomies and non-unions of the distal fibula, particularly in osteopenic bone.
(6) **Technological characteristics Comparison**	The LOQTEQ® Distal Fibula Plate and the legally marketed predicated devices have similar indications, dimensions, geometry and materials. The LOQTEQ® Distal Fibula Plate 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 same 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.

Summary of Non-clinical tests:

Type of test:

"Mechanical Safety of aap Implantate AG – LOQTEQ® Distal Fibula Plate, Static and Dynamic 4-point-bending test of bone plates according to ASTM F 382-99 (Reapproved 2008)."

"Mechanical properties of metallic bone screws in accordance with ASTM F543-13e1"

"Biocompatibility of Implants and Instruments of aap LOQTEQ® Distal Fibula Plates and Screw"

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 screws fulfil the relevant demands of ASTM F543-13.

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® Distal Fibula Plates and Screws 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.