DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 23, 2016

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

Re: K161696
Trade/Device Name: aap LOQTEQ® Distal Lateral Humerus 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 16, 2016
Received: October 18, 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)*

K161696

Device Name

aap LOQTEQ® Distal Lateral Humerus Plate 2.7/3.5

Indications for Use *(Describe)*

Intra-articular fractures, supracondylar fractures, osteotomies and non-unions of the distal humerus

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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Date November/22/2016

(2)

Trade Name aap LOQTEQ® Distal Lateral Humerus Plate 2.7/3.5

Common Name LOQTEQ® Distal Lateral Humerus Plate

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 Company Synthes (USA):
3.5 MM LCP Distal Humerus System under the premarket notification K033995

(4)

Device Description The aap LOQTEQ® Distal Lateral Humerus Plate 2.7/3.5 is part of the LOQTEQ® Elbow System (K132787 and K140607), 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.
aap already offers a system of two plates for treatment of distal Humerus fractures: these are the anatomical shaped Plates LOQTEQ® Distal Dorsolateral Humerus Plate and LOQTEQ® Distal Medial Humerus Plate. Typically these devices are used together for one fracture and are placed under 90° orientation. The devices are already registered under the premarket notification K132787. Depending on the surgeons education some doctors prefer to use a different placement of the two plates.
Therefore aap wants to add a further plate for the use in the identical intended use: this is the LOQTEQ® Distal Lateral Humerus Plate which is also used together with the LOQTEQ® Distal Medial Humerus Plate (see surgical approach above). In some rare indications this new device might be used as a standalone treatment.

	The anatomically performed plates are available as right and left version and in different lengths and with several shaft holes. The tapered end of the plate enables tissue-conserving, submuscular insertion. The tip of the shaft is tapered to allow a minimally invasive surgical technique. The bottom of shaft area is structured and tunnelled by cross grooves to minimize bone contact. All shaft holes, with the exception of the elongated hole are compatible with unidirectional locking screws as well as cortical screws. 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 round locking holes are suitable for locking screws as well as cortical screws. The locking screws allow evening catching very small fragments. The design of the so-called glide holes allows angle stable fixation and proximal compression of bone fragments at the same time if LOQTEQ® Cortical Screws are used. The use of standard cortical bone screws leads to a non-angle stable fixation. A compression of the bone fragments can be realised, if the screws are positioned eccentric inside the glide hole. If the screws are placed directly in the locking part of the gliding hole, no compression occurs. The aap LOQTEQ® Distal Lateral Humerus Plate 2.7/3.5 consists of: LOQTEQ® Distal Lateral Humerus Plate, right/left, 2/3/5/7/11 holes LOQTEQ® Cortical Screw 2.7, small head, T8, self-tapping LOQTEQ® Cortical Screw 3.5, T15, self-tapping Cortical Screw 2.5, small head, T8, self-tapping Cortical Screw 3.5, self-tapping Set of Instruments aap LOQTEQ® Distal Lateral Humerus Plate
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**	**aap LOQTEQ® Distal Lateral Humerus Plate 2.7/3.5:** Intra-articular fractures, supracondylar fractures, osteotomies and non-unions of the distal humerus
(6a) **Technological characteristics Comparison**	The LOQTEQ® Distal Lateral Humerus Plate and the legally marketed predicated devices have similar indications, dimensions, geometry and materials. The LOQTEQ® Distal Lateral Humerus Plate is technologically substantially equivalent to the predicate devices according to the Decision-Making Process for 510(k)s: Predicate device is legally marketed

1. The devices have the identical intended use
2. The devices have 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

An engineering analysis was used to show substantial equivalence of the subject device to the predicate device in terms mechanical performance, including bending strength, bending stiffness, bending structural stiffness, and fatigue strength.

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