



January 21, 2016

aap Implantate Ag
Dr. Christian Zietsch
Director Quality Assurance and Regulatory Affairs
Lorenzweg 5
Berlin, D-12099
GERMANY

Re: K153034

Trade/Device Name: aap LOQTEQ[®] VA Radius Set 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: October 20, 2015
Received: October 23, 2015

Dear Dr. Zietsch:

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 Parts 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" (21CFR 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 yours,

Lori A. Wiggins -S

for

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K153034

Device Name
aap LOQTEQ® VA Radius Set 2.5

Indications for Use (Describe)

LOQTEQ® VA Volar Distal Radius Plate 2.5,
LOQTEQ® VA Distal Radius Straight Plate 2.5,
LOQTEQ® VA Distal Radius L-Plate 2.5

- Fixation of complex intra-articular and extra-articular fractures and osteotomies of the distal radius

LOQTEQ® VA Distal Ulna Plate 2.5,
LOQTEQ® VA Distal Ulna Hook Plate 2.5

- Fractures and osteotomies of the distal ulna

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 Implantate AG
aap LOQTEQ® VA Radius Set 2.5
 Section 5 Summary of Safety and Effectiveness

5. Summary of Safety and Effectiveness

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

Company Contact: Dr. Christian Zietsch
 Phone: +49-30-750-19 - 193
 Fax: +49-30-750-19 – 111

Date Jan/21/2016

Trade Name: aap LOQTEQ® VA Radius Set 2.5

Common Name: Variable Angle Distal Radius/Ulna Plates and Screws 2.5

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

Predicate devices Synthes (USA) Variable Angle LCP Dorsal Distal Radius System under the premarket notification K102694 (Dec 09, 2010)
 Synthes (USA) LCP Diaphyeal-Metaphyseal (Dia-Meta) Volar Distal Radius Plate under the premarket notification K070946 (Jun 06, 2007)
 Synthes (USA) VA LCP Two-Column Volar Distal Radius Plates under the premarket notification K083694 (MAR 06, 2009)
 Medartis AG APTUS Ulna Plates under the premarket notification K103332 (Jan 24, 2011).

Device Description: The aap LOQTEQ® VA Radius Set 2.5 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. If the plates are used in conjunction with locking screws, a so called internal fixator will be realized (internal fixation).

The aap LOQTEQ® VA Radius Set 2.5 incorporates:

- LOQTEQ® VA Volar Distal Radius Plate 2.5, narrow/broad, right/left
- LOQTEQ® VA Volar Distal Radius Plate 2.5, narrow, XL, right/left
- LOQTEQ® VA Distal Radius Straight Plate 2.5
- LOQTEQ® VA Distal Radius L-Plate 2.5, right/left
- LOQTEQ® VA Distal Ulna Plate 2.5
- LOQTEQ® VA Distal Ulna Hook Plate 2.5
- LOQTEQ® VA Cortical Screw 2.5, T8
- Cortical Screw 2.5, small head, T8, self-tapping
- Set of Instruments LOQTEQ® VA Distal Radius Set 2.5

Material:

Ti6Al4V (ASTM F136 or ISO 5832-3)
 unalloyed Titanium (ASTM F67 or ISO 5832-2)

Indications:

The aap LOQTEQ® VA Volar Distal Radius Plate 2.5, LOQTEQ® VA Distal Radius Straight Plate 2.5, LOQTEQ® VA Distal Radius L-Plate 2.5 are intended for **fixation of complex intra-articular and extra-articular fractures and osteotomies of the distal radius.**

The aap LOQTEQ® VA Distal Ulna Plate 2.5, LOQTEQ® VA Distal Ulna Hook Plate 2.5 are intended **for fractures and osteotomies of the distal ulna.**

Substantial Equivalence

The Substantial Equivalence of the new device and the predicate device is based on similar intended use, design, functionality, components and materials in use. Documentation including mechanical testing to show the substantial equivalence has been provided with this submission.

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: Static and dynamic system tests, representing worst case scenario with respect to clinical use.

Screw tests according to ASTM F543 – 13.

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 subject device is safe and effective, and whose performance meets the requirements of its pre-defined acceptance criteria and intended uses.

Documentation regarding the mechanical testing to show the substantial equivalence and safety and effectiveness has been provided with this submission.