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

March 24, 2015

*aap* Implantate AG
Dr. Christian Zietsch
Manager, Regulatory Affairs
Lorenzweg 5, D-12099 Berlin
GERMANY

Re: K132787
Trade/Device Name: aap LOQTEQ® Elbow System
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: September 26, 2013
Received: October 7, 2013

Dear Dr. Zietsch:

This letter corrects our substantially equivalent letter of December 24, 2013.

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″ (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

## Indications for Use Statement

510(k) Number (if known): K132787

## Device Name: *aap* LOQTEQ® Elbow System

## Indications for Use:

The aap LOQTEQ® Elbow System is indicated for:

- intra-articular fractures of the distal Humerus
- supracondylar fractures of the distal Humerus
- osteotomies, and non-unions of the distal Humerus

| Prescription Use X (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132787

*aap* Implantate AG
***aap* LOQTEQ® Elbow System**

# Summary of Safety and Effectiveness

| | |
|---|---|
| **Sponsor:** | ***aap* Implantate AG**<br>Lorenzweg 5<br>D-12099 Berlin Germany |
| **Company Contact**: | Dr. Christian Zietsch<br>Phone:+49-30-750-19 -193<br>Fax: +49-30-750-19 - 111 |
| **Date** | March / 12 / 2015 |
| **Trade Name:** | aap LOQTEQ® Elbow System |
| **Common Name:** | Distal Humerus System |
| **Classification Name and Reference:** | 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories – Class II and 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener - Class II |
| **Device Product Code and Panel Code:** | Orthopedics/87/ HRS: Plate, Fixation, Bone<br>Orthopedics/87/ HWC: Screw, Fixation, Bone |
| **Predicate device:** | Synthes (USA) 3.5 mm LCP Distal Humerus System under the premarket notification K033995 (Mar 1, 2004) |
| **Device Description:** | The aap LOQTEQ® Elbow System consists of bone plates and bone screws, to be implanted by a surgeon in order to achieve an internal fixation of bone fragments of the distal humerus. If the plates are used in conjunction with locking screws, a so called internal fixator will be realized (internal fixation).<br><br>The aap LOQTEQ® Elbow System consists of:<br>• LOQTEQ® Distal Dorsolateral Humerus Plate (left and right)<br>• LOQTEQ® Distal Medial Humerus Plate (left and right)<br>LOQTEQ® Cortical Screw 2.7, small head T8, self-tapping<br>• Cortical Screw 2.5, small head T8, self-tapping<br>• LOQTEQ® Cortical Screw 3.5, T15, self-tapping<br>• Cortical Screw 3.5, self-tapping<br>• Set of Instruments aap LOQTEQ® Elbow System |
| **Material:** | Implants are made of Ti6Al4V (ASTM F136 or ISO 5832-3) |
| **Indications:** | The aap LOQTEQ® Elbow System is indicated for:<br>- intra-articular fractures of the distal Humerus<br>- supracondylar fractures of the distal Humerus<br>- osteotomies, and non-unions of the distal Humerus |

**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 and safety and effectiveness has been provided with this submission.

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

Non-clinical tests have been performed and show the effectiveness and safety 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.

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 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.