

SEP 6 2012

## Summary of Safety and Effectiveness

**Sponsor:** aap Implantate AG  
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**Date:** December 5, 2011

**Trade Name:** aap LOQTEQ® Large Fragment Set

**Common Name:** Large Fragment Set

**Classification:**

**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  
Orthopedics/87/ HWC: Screw, Fixation, Bone

**Predicate device:** Large Fragment LCP Instrument and Implant Set of Synthes (USA) under the premarket notification K000682 (May – 1, 2000). At this time the system was called Synthes Large Fragment Dynamic Compression Locking (DCL) System.

**Device Description:** Bone plates and screws are used for fixation of bone fragments, i.e., for treatment of bone fractures and other bone injuries. Bone plates are fixed by the use of bone screws. Bone plates and bone screws are implants. If the plates are used in conjunction with locking screws, a so called internal fixator will be realized (internal fixation). The LOQTEQ® Large Fragment Set consists of:

- LOQTEQ® Narrow Plate 4.5,
- LOQTEQ® Broad Plate 4.5,
  
- LOQTEQ® Cortical Screw 4.5, T25, self-tapping
- Cortical Screw 4.5, self-tapping
  
- Set of Instruments, Large Fragment Set

**Material:** Plates are made of cp Titanium (ASTM F67 or ISO 5832-2)  
Screws are made of Ti6Al4V (ASTM F136 or ISO 5832-3)

**Indications:**

The aap LOQTEQ® Large Fragment Set is intended for:  
Fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation of non-unions or malunions.

**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 4-point-bending test of bone plates according to ASTM F 382-99.

Assessment of test results:

Substantial equivalence with respect to the mechanical performance of the aap plates 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.



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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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



*MS* Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use Statement

510(k) Number (if known):     K113648    

### Device Name: LOQTEQ<sup>®</sup> Large Fragment Set

#### Indications for Use:

The aap LOQTEQ<sup>®</sup> Large Fragment Set includes Narrow and Broad Plates 4.5. The plates accept 4.5 mm locking screws and 4.5 mm cortical screws.

The aap LOQTEQ<sup>®</sup> Large Fragment Set is intended for:  
Fixation of various long bones, such as the humerus, femur and tibia. It is also for use in fixation of osteopenic bone and fixation of non-unions or malunions.

Prescription Use   X  
(Part 21 CFR 801 Subpart D)

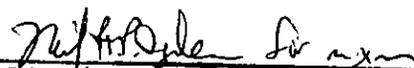
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

Division of Surgical, Orthopedic,  
and Restorative Devices

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