



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

April 29, 2015

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

Re: K150974

Trade/Device Name: aap Cortical Screws 1.5, Self-tapping, aap Cortical Screws 1.5, Self-tapping, Titanium

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener

Regulatory Class: Class II

Product Code: HWC

Dated: April 10, 2015

Received: April 13, 2015

Dear Dr. Christian 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 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 yours,

**Mark N. Melkerson -S**

Mark 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)

K150974

Device Name

aap Cortical Screws 1.5, self-tapping  
aap Cortical Screws 1.5, self-tapping, titanium

Indications for Use (Describe)

The devices are intended to treat fractures of various bones, including the clavicle, scapula, pelvis, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, and phalanges) according to the standard of the AO Foundation (AO Principles of Fracture Management).

All aap bone screws are for single use only and are not intended for any spinal fixation procedures.

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

## Summary of Safety and Effectiveness

|  |   |
|--|---|
| <b>Sponsor:</b>                            | <b>aap Implantate AG</b><br>Lorenzweg 5<br>D-12099 Berlin, Germany  |
| <b>Company Contact:</b>                    | Dr. Christian Zietsch<br>Phone: +49-30-750-19 -193<br>Fax: +49-30-750-19 - 111  |
| <b>Date</b>                                | April/10/ 2015  |
| <b>Trade Name:</b>                         | aap Cortical Screws 1.5, self-tapping<br>aap Cortical Screws 1.5, self-tapping, titanium  |
| <b>Common Name:</b>                        | Screw, fixation, bone   |
| <b>Classification Name and Reference:</b>  | 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener – Class II   |
| <b>Device Product Code and Panel Code:</b> | Orthopedics/87/ HWC   |
| <b>Predicate device:</b>                   | The aap Cortical Screw 1.5, self-tapping is substantially equivalent to aap Screw Implants under the premarket notification K072411 (Mar 20, 2008).   |
| <b>Purpose of Submission</b>               | This special 510(k) premarket notification is submitted to obtain clearance for the aap Cortical Screws 1.5, self-tapping (titanium)  |
| <b>Device Description:</b>                 | <p>The aap Cortical Screws 1.5, self-tapping are bone screws, to be implanted by a surgeon in order to achieve an internal fixation of bone fragments typically after fractures or osteotomies. The screws can be used along with the aap bone plate as well as lag screws, to hold together fragments of bone. The devices are made of Implant Stainless Steel or Titanium alloy.</p> <p>Variations of the aap Cortical Screw 1.5, self-tapping</p> <ul style="list-style-type: none"> <li>• Cortical Screw 1.5, self-tapping</li> <li>• Cortical Screw 1.5, self-tapping, Titanium</li> </ul> |
| <b>Material:</b>                           | Implants are made of Stainless Steel (ASTM F138 or ISO 5832-1) or Ti6Al4V (ASTM F136 or ISO 5832-3)   |

aap Implantate AG

**aap Cortical Screws 1.5, self-tapping**

**Indications:**

The devices are intended to treat fractures of various bones, including the clavicle, scapula, pelvis, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, and phalanges) according to the standard of the AO Foundation (AO Principles of Fracture Management).

All aap bone screws are for single use only and are not intended for any spinal fixation procedures.

**Substantial Equivalence Summary**

The Substantial Equivalence of the new device and the predicate device is based on similar intended use, design, functionality, components, technological characteristics and materials in use.

Documentation to show the substantial equivalence has been provided with this submission.

Engineering rationale have been prepared and show the substantial equivalence of the device.

Summary of Engineering rationale:

Any differences between the subject devices and the predicates are considered minor and do not raise questions concerning safety and effectiveness.