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

September 12, 2014

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

Re: K141949
Trade/Device Name: *aap* Cortical Screws 3.5, 4.5
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 8, 2014
Received: August 11, 2014

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" (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): K141949

Device Name: *aap* Cortical Screws 3.5, 4.5

Indications for Use:

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.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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	August/08/ 2014
Trade Name:	*aap* Cortical Screws 3.5, 4.5
Common Name:	Cortical Screws 3.5, 4.5Clavicle
Classification Name and Reference:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener – Class II
Device Product Code and Panel Code:	Orthopedics/87/ HWC
Predicate device:	The aap Cortical Screw 3.5, 4.5 are substantially equivalent to aap Screw Implants (Cortical Screw 3.5, self-tapping, Titanium and Cortical Screw 4.5, self-tapping, Titanium) under the premarket notification K072411 (Mar 20, 2008), aap Cortical Screw 3.5, small head , self-tapping, Titanium under the premarket notification K113652 (Aug 30, 2012) and Cortical Screw 4.5, small head, self-tapping, Titanium under the premarket notification K113648 (Sep. 6, 2012).
Device Description:	The aap Cortical Screws 3.5, 4.5 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 as non locking screws along with the aap LOQTEQ® System as well as lag screws, to hold together fragments of bone. The devices are made of Titanium alloy. Variations of the aap Cortical Screw 3.5, 4.5: • Cortical Screw 3.5, T15, self-tapping, Titanium • Cortical Screw 4.5, T25, self-tapping, Titanium
Material:	Implants are made of Ti6Al4V (ASTM F136 or ISO 5832-3)

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

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 and engineering analysis (dimensions and material) 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.

<u>Summary of Non-clinical tests:</u>

Type of test:
Mechanical properties of metallic bone screws in accordance with ASTM F543

Tests performed:
The Torsional Properties of Metallic Bone Screws, here Torsional Yield Strength, Maximum Torque, and Breaking Angle, the Driving Torque Properties, here Insertion and Removal Torque as well as the Axial Pullout strength of the screws have been determined according to ASTM F543 (Annex A1, A2 and A3).

Assessment of test results:
Substantial equivalence with respect to the mechanical performance of the aap screws could be stated due to the test results gained. The minimum acceptable values for Maximum Torque and Breaking Angle as given in Annex A5 of ASTM F543 have been reached.
The subject device is substantial equivalent, and whose performance meets the requirements of its pre-defined acceptance criteria and intended uses.

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