510 (K) **Summary of Safety and Effectiveness**

APR 2 2 2013

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	February/28/ 2013
Trade Name:	*aap* Cannulated Screw 2.0
Common Name:	Cannulated Screw 2.0
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/ HWC: Screw, Fixation, Bone Orthopedics/87/ HTN: Washer, Bolt Nut
Predicate device:	Asnis™ Micro Cannulated Screw System from Stryker (former Howmedica) under the premarket notification K071092 (May 11, 2007)
Device Description:	Cannulated Screws are used for fixation of bone fragments, i.e., for treatment of bone fractures and other bone injuries. Cannulated Screws with a diameter of 2.0 mm are manly in use for foot and hand surgery. The aap Cannulated Screw 2.0 consists of: • Cannulated Screw 2.0, Long thread • Cannulated Screw 2.0, Short thread • Washer • Set of Instruments Cannulated Screws
Material:	Implants made of Ti6Al4V (ASTM F136 or ISO 5832-3) or Implants made of stainless steel (ASTM F138 or ISO 5832-1)
Indications:	The aap Cannulated Screw 2.0 is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.
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.

aap Implantate AG
***aap* Cannulated Screw 2.0**

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:
Mechanical tests of Screws acc. to ASTM F543-07

Assessment of test results:
The Screws fulfil the relevant requirements of ASTM F543-07 and 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.

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

April 22, 2013

aap Implantate AG
% Dr. Christian Zietsch
Manager RA
Lorenzweg 5
D-12099 Berlin Germany

Re: K130590
Trade/Device Name: aap Cannulated Screw 2.0
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: February 28, 2013
Received: March 14, 2013

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 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 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" (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 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,

Erin D. Keith

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): K130590

Device Name: aap Cannulated Screw 2.0

Indications for Use:

The aap Cannulated Screw 2.0 is intended for fracture fixation of small and long bones and of the pelvis. The system is not intended for spinal use.

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)

Elizabeth L. Frank -S

Division of Orthopedic Devices