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510(k) Summary

JUN - 2 2011

**Medartis AG**  
**APTUS® Cannulated Compression Screws**

March 4, 2011

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: APTUS® Cannulated Compression Screws  
Common Name: Screw, fixation, bone

Classification Regulations: Smooth or threaded metallic bone fixation fastener  
21 CFR 888.3040, Class II

Product Codes: HWC

Classification Panel: Orthopedic Products Panel  
Reviewing Branch: Orthopedic Devices Branch

INTENDED USE

APTUS® Cannulated Compression Screws are indicated for the treatment of fractures, osteotomies and arthrodeses of bones e.g. in the hand, wrist, elbow, foot with the appropriate screw size.

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**DEVICE DESCRIPTION**

APTUS Cannulated Compression Screws are headless screws provided in diameters of 2.2 and 3.0 mm, overall lengths from 10 to 40 mm, and threaded lengths from 3.5 to 18 mm. APTUS Cannulated Compression Screws have head and shaft threads with different pitch thus creating compression of the bone segments upon insertion of the screw. APTUS Cannulated Compression Screws are made of titanium alloy conforming to ASTM F136.

**EQUIVALENCE TO MARKETED DEVICE**

The APTUS Cannulated Compression Screws are substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Synthes (USA), Synthes (USA) 2.4 mm Cannulated Compression Screw, cleared under K021556;

Synthes (USA), Synthes (USA) 3.0 mm Headless Compression Screws, cleared under K050636;

OsteoMed L.P., OsteoMed Headless Cannulated Screw System, cleared under K063298;  
Wright Medical Technology, Inc., CHARLOTTE™ 7.0 MUC Screw and Washer, cleared under K070525;

Wright Medical Technology, Inc., CHARLOTTE™ High Demand Compression Screw, cleared under K043281; and

Howmedica Osteonics Corporation (now Stryker Corporation), Asnis™ III Cannulated Screw System, cleared under K071092.

APTUS Cannulated Compression Screws and the predicate devices are all compression screws having similar indications for use and are made of the same or similar materials. The subject and predicate devices are similar in overall shape and design, and encompass a similar range of physical dimensions, including screw thread diameter, overall length, and threaded length.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

Performance data are provided to demonstrate substantial equivalence. This includes detailed dimensional analysis of the subject and predicate screw designs, and testing of the subject and predicate screw designs.

Overall, APTUS Cannulated Compression Screws have the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principles,
- incorporates the same basic designs,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.



Food and Drug Administration  
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Re: K110658

Trade/Device Name: APTUS® Cannulated Compression Screws  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HWC  
Dated: March 4, 2011  
Received: March 7, 2011

Dear Dr. Thomas:

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.

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.

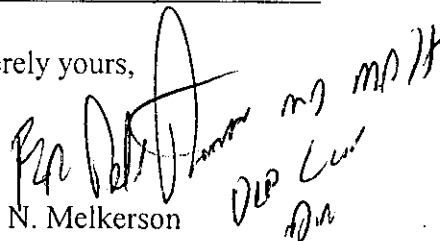
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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,

Handwritten signature of Mark N. Melkerson in black ink. The signature is stylized and includes the initials 'MS' and 'MD' to the right of the main signature.

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

Enclosure

