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510(k) Summary

JUN - 2 2011

Medartis AG
APTUS® Cannulated Compression Screws

March 4, 2011

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Medartis AG Hochbergerstrasse 60E CH-4057 Basel, Switzerland Telephone: +41 61 633 34 34 Fax: +41 61 633 34 00
Official Contact:	Ulrike Jehle Regulatory Affairs Manager, Medartis AG
Representative/Consultant:	Kevin A. Thomas, PhD Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 Email: kthomas@paxmed.com flarson@paxmed.com

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® Canulated 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Medartis AG
% PaxMEd International, LLC
Kevin A. Thomas, PhD
11234 El Camino Real, Suite 200
San Diego, California 92130

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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" (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,

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

510(k) Number: K110658

Device Name: APTUS® Cannulated Compression Screws

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APTUS® Canulated 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.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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