# 510(k) Summary

DEC 18 2013

## Medartis AG

## APTUS® Cannulated Compression Screws 5.0, 7.0

November 11, 2013

ADMINISTRATIVE INFORMATION

| | |
|---|---|
| Manufacturer Name | Medartis AG<br>Hochbergerstrasse 60E<br>CH-4057 Basel, Switzerland<br>Telephone: +41 61 633 34 34<br>Fax: +41 61 633 34 00 |
| Official Contact | Andrea Schweizer<br>Group Manager Compliance & Vigilance |
| Representative/Consultant | Allison C. Komiyama, Ph.D.<br>Floyd G. Larson<br>PaxMed International, LLC<br>12264 El Camino Real, Suite 400<br>San Diego, CA 92130<br>Telephone: +1 (858) 792-1235<br>Fax: +1 (858) 792-1236<br>Email: akomiyama@paxmed.com<br>flarson@paxmed.com |

DEVICE NAME AND CLASSIFICATION

| | |
|---|---|
| Trade/Proprietary Name | APTUS® Cannulated Compression Screws |
| Common Name | Screw, fixation, bone |
| Classification Name | Smooth or threaded metallic bone fixation fastener |
| Classification Regulations | 21 CFR 888.3040, Class II |
| Product Code | HWC, HTY |
| Classification Panel | Orthopedic Products Panel |
| Reviewing Branch | Orthopedic Devices Branch |

INTENDED USE

APTUS® Cannulated Compression Screws 5.0, 7.0 are intended for the treatment of fractures, osteotomies and arthrodeses of bones with the appropriate screw size.

DEVICE DESCRIPTION

APTUS® Cannulated Compression Screws 5.0, 7.0 are headless screws intended for the treatment of fractures, osteotomies and arthrodeses of bones. The design of the screw, incorporating various diameters, threads, pitch threads on the head and tip, provides compression of the bone segments upon insertion of the screw. The submission includes the associated K-wires, intended to be used for internal fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of the implants.

APTUS Cannulated Compression Screws 5.0, 7.0 are available in two diameters (5.0 mm and 7.0 mm) and come in partially-threaded or fully-threaded designs. The 5.0 mm screws are provided in overall lengths ranging from 30 to 70 mm. The 7.0 mm screws are provided in overall lengths ranging from 40 to 140 mm. The 5.0 and 7.0 mm screws are used with the 1.6 and 2.2 mm diameter K-wires, respectively.

APTUS® Cannulated Compression Screws 5.0, 7.0 are made of titanium alloy conforming to ASTM F136 *Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)* and the K-wires are made of stainless steel conforming to ASTM F138 *Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).*

EQUIVALENCE TO MARKETED DEVICE

APTUS® Cannulated Compression Screws 5.0, 7.0 are substantially equivalent in indications and design principles to the following predicate devices:

- Medartis AG, APTUS® K-Wire System (K092038)
- Medartis AG, APTUS® Cannulated Compression Screws (K110658)
- Synthes (USA), Synthes 4.5 mm and 6.5 mm Headless Compression Screws (K080943)
- Synthes (USA), Synthes 7.0/7.3 mm Cannulated Screws (K962011)
- Wright Medical Technology, Inc., DARCO® Headless Compression Screw (K080850)

APTUS® Cannulated Compression Screws 5.0, 7.0 have similar designs and identical materials as those cleared under K092038 and K110658. The subject device is similar in indications to those cleared in K110658, K080943, K962011, and K080850. The designs and dimensions of the subject device are similar and within the range of those cleared in K080943, K962011, and K080850.

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: engineering analysis, dimensional analysis and mechanical testing. APTUS® Cannulated Compression Screws 5.0, 7.0 were subjected to mechanical performance testing following the FDA recognized standard ASTM F543 *Standard Specification and Test Method for Metallic Bone Screws*. Side-by-side testing of screws was performed utilizing the subject and predicate devices cleared in K080943, K962011, and K080850.

Clinical data were not submitted in this premarket notification.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy. The data included in this submission demonstrates substantial equivalence to the predicate devices listed above.

Overall, APTUS® Cannulated Compression Screws 5.0, 7.0 has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- 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 Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2013

Medartis AG
% Allison C. Komiyama, Ph.D.
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K133460
Trade/Device Name: APTUS® Cannulated Compression Screws 5.0, 7.0
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTY
Dated: November 11, 2013
Received: November 12, 2013

Dear Dr. Komiyama:

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 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. 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,

Ronald P. Jean -S for

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

Enclosure

## Indications for Use

510(k) Number: K133460

Device Name: APTUS® Cannulated Compression Screws 5.0, 7.0

Indications for Use:

APTUS® Cannulated Compression Screws 5.0, 7.0 are intended for the treatment of fractures, osteotomies and arthrodeses of bones 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)



Elizabeth L. Frank -S

Division of Orthopedic Devices