510(k) Summary
Medartis AG
APTUS® Wrist Arthrodesis Plates
K112169

December 29, 2011

ADMINISTRATIVE INFORMATION

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	APTUS® Wrist Arthrodesis Plates
Common Names:	Plate, fixation, bone; Screw, fixation, bone
Classification Names:	Single/multiple component metallic bone fixation appliances and accessories
Classification Regulations:	21 CFR 888.3030, Class II
Product Codes:	HRS
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

APTUS® Wrist Arthrodesis Plates are indicated for wrist arthrodesis.

DEVICE DESCRIPTION

The APTUS® Wrist Arthrodesis Plates system is intended to be used for internal fixation of wrist fusions and consists of three titanium locking plates. The plates are secured using previously cleared titanium screws. APTUS Wrist Arthrodesis Plates are provided in various sizes.

EQUIVALENCE TO MARKETED DEVICE

APTUS® Wrist Arthrodesis Plates 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:

Kinetikos Medical Inc., KMI™ Wrist Fusion System, cleared under K990094,

Synthes (USA), Synthes (USA) Small Titanium Wrist Fusion Plate cleared under K023879,

Synthes (USA), Synthes (USA) LCP Wrist Fusion Plates cleared under K042355,

Synthes (USA), Synthes Straight Wrist Fusion Plate cleared under K011458,

Synthes (USA), Synthes USA) Wrist Fusion Plate cleared under K000558, and

Medartis, Inc., APTUS® Titanium Fixation System cleared under K051567.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject and predicate devices are all fabricated from the same or similar materials and share similar design characteristics. The subject and predicate devices encompass the same or comparable ranges of physical dimensions, are packaged using the same or similar materials, and are to be sterilized by the same methods. Any differences in the technological characteristics do not raise new issues of safety or efficacy.

Performance data provided to demonstrate substantial equivalence include detailed dimensional analysis of the subject and predicate plate designs, and moment of inertia analysis of the subject and predicate plate design. Screw pull-out testing and engineering analysis were performed to demonstrate that the distal attachment of the subject device plates (carpal bones) is comparable to that of the predicate device plates (third metacarpal bone).

Overall, APTUS Wrist Arthrodesis Plates have the following similarities to the predicate devices:

- have the same intended use,
- use the same operating principles,
- incorporate the same basic designs,
- incorporate the same or very similar materials, and
- have similar packaging and are 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
Dr. Kevin A. Thomas
Vice President and Director of Regulatory Affairs
11234 El Camino Real, Suite 200
San Diego, California 92130

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Re: K112169
Trade/Device Name: Aptus® Wrist Arthrodesis Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: December 29, 2011
Received: December 30, 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,

for 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: K112169

Device Name: APTUS® Wrist Arthrodesis Plates

Indications for Use:

APTUS® Wrist Arthrodesis Plates are indicated for wrist arthrodesis.

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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