510(k) Summary

DEC 10 2010

APTUS® 1.5 TriLock
Special 510(k): Device Modification

October 5, 2010

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Medartis AG Hochbergerstrasse 60E CH-4057 Basel, Switzerland Telephone: +41 61 633 34 34 Fax: +41 61 633 34 00
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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® 1.5 TriLock
Common Name:	Plate, fixation, bone
Classification Regulations:	Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3030 Class II
Product Code	HRS
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The APTUS® 1.5 TriLock is intended for use in hand and forearm fractures, osteotomies and arthrodeses.

APTUS® Hand group:

- Management of the fractures of the distal, middle and proximal phalanges and metacarpals
- Management of all types of transversal fractures, spiral fractures, fractures near joints with or without joint involvement, shaft factures, comminuted fractures, dislocation fractures, avulsion fractures
- DIP and PIP arthrodoses

APTUS® Radius 2.5 group:

- Management via radio volar approach of extra-articular extension and flexion fractures, articular extension and flexion fractures, correction osteotomies for badly healed radius fractures
- Management via dorsal approach of rare extension fractures that cannot be adequately reduced via volar approach, procedures for which the soft tissue conditions make a volar approach very difficult or impossible, correction osteotomies requiring stabilization from the dorsal side, carporadial fusions.

DEVICE DESCRIPTION

The APTUS 1.5 TriLock consists of titanium TriLock plates and titanium TriLock screws with locking function. The system is intended to be used for internal fixation of small bones. The 1.5 TriLock plates may also be used with existing standard 1.2 mm (thread diameter) and 1.5 mm (thread diameter) cortical bone screws cleared under APTUS® Titanium Fixation System, K051567. The only modifications being made in this submission are the addition of eight (8) plates, all 0.8 mm in thickness, having various screw hole and design configurations, and the addition of ten (10) screws, all having a major thread diameter of 1.5 mm, all with a locking head design, provided in lengths ranging from 4 mm to 13 mm in 1 mm increments. The technological differences between the subject device and the predicate include a change in the thickness of the plates and the change in plate configurations and the change in screw head design to allow locking to the plates.

EQUIVALENCE TO MARKETED PRODUCT

Medartis AG demonstrated that, for the purposes of FDA's regulation of medical devices, the APTUS 1.5 TriLock is substantially equivalent in indications and design principles to the following predicate device, which has been determined by FDA to be substantially equivalent to preamendment devices:

APTUS® Titanium Fixation System, K051567

The subject device has the same intended use as the predicate device and has the same Indications for Use Statement as the predicate cleared under K051567.

The subject device has the same technological characteristics as the predicate device. The subject and predicate devices are all fabricated from the same materials (commercially pure titanium and titanium alloy) and share similar design characteristics. The subject and predicate devices are packaged using the same materials and are to be sterilized by the same methods.

Performance data provided to demonstrate substantial equivalence included: detailed dimensional analysis of the subject and predicate screw designs; insertion, shear, and pullout testing of the subject and predicate screws; and fatigue testing of the subject and predicate plate designs.

In summary, the APTUS 1.5 TriLock has the following similarities to the predicate device:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same materials, and
- is packaged and 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
c/o Mr. Kevin A. Thomas
Regulatory Consultant
Hochbergerstrasse 60E
CH-4057 Basel, Switzerland

DEC 10 2010

Re: K102537
Trade/Device Name: APTUS 1.5 TriLock
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: November 5, 2010
Received: November 11, 2010

Dear Mr. 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. 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 such 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

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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

DEC 1 0 2010

510(k) Number (if known): K102537

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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)

for M. Melkerson

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

510(k) Number K102537