



Food and Drug Administration  
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Medacta International SA  
% Elizabeth Rose, MST, RAC  
Regulatory Affairs Manager  
Mapi USA, Inc.  
2343 Alexandria Drive, Suite 100  
Lexington, Kentucky 40504

August 1, 2017

Re: K171369  
Trade/Device Name: M.U.S.T. MINI Posterior Cervical Screws System  
Regulatory Class: Unclassified  
Product Code: NKG, KWP  
Dated: May 10, 2017  
Received: May 10, 2017

Dear Ms. Rose:

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

**Mark N. Melkerson -S**

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 (if known)

K171369

Device Name

M.U.S.T. MINI Posterior Cervical Screws System

Indications for Use (Describe)

The M.U.S.T. Mini posterior cervical screws system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The M.U.S.T. Mini posterior cervical screws system is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the M.U.S.T. Mini posterior cervical screws system may be connected to the M.U.S.T. system rods with the M.U.S.T. Mini rod connectors. Transition rods with differing diameters may also be used to connect the M.U.S.T. Mini posterior cervical screws system to the M.U.S.T. system. Refer to the M.U.S.T. system package insert for a list of the M.U.S.T. indications of use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 3.0 510(k) Summary

### I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager  
Consultant: Elizabeth Rose, Regulatory Affairs Manager, Mapi USA, Inc.  
Date Prepared: May 10, 2017  
Date Revised: July 25, 2017

### II. Device

Device Proprietary Name:	M.U.S.T. MINI Posterior Cervical Screws System
Common or Usual Name:	Posterior Cervical System
Classification Name:	Orthosis Cervical Pedicle Screw Spinal Fixation
Primary Product Code:	NKG
Secondary Product Code:	KWP
Device Classification	Unclassified

### III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary Predicate:

- Synapse Occipital-Cervical-Thoracic (OCT) System, K142838, Synthes USA Products, LLC (also referred to as Synthes' Synapse System)

Additional Predicates

- Synapse System, K070573, Synthes Spine Co. LP, (also referred to as Synthes' Synapse System)
- Synthes Cervifix/Axon, K023675, Synthes (USA), (also referred to as Synthes' Axon System)
- Synthes Cervifix System, K991089, Synthes Spine, (also referred to as Synthes' Axon System)
- Vertex Reconstruction System, Vertex Select Reconstruction System, K123906, Medtronic Sofamor Danek USA, Inc. (also referred to as Medtronic's Vertex)
- Exactech Gibralt Spinal System, K110197, Exactech, Inc.
- Blackstone Posterior Cervical System, K030197, Blackstone Medical, Inc.

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- Pioneer Posterior Occipito-Cervico-Thoracic (OCT) System, K121725, Pioneer Surgical Technology
  - M.U.S.T. Extension, K132878, Medacta International SA (also known as M.U.S.T. Pedicle Screws System)
  - M.U.S.T. Pedicle Screws System, K141988, Medacta International SA
  - M.U.S.T. Pedicle Screws System, K153664, Medacta International SA
  - M.U.S.T. Pedicle Screws System, K162061, Medacta International SA
  - M.U.S.T. Pedicle Screw System Extension - Straight Connectors and Additional Screws, K171170, Medacta International SA

#### **IV. Device Description**

The purpose of this submission is to gain clearance for the M.U.S.T. MINI Posterior Cervical Screws System. The M.U.S.T. MINI Posterior Cervical Screws System is a multi-component system constructed from titanium and CoCrMo materials, consisting of rods that are longitudinally interconnected and anchored to adjacent vertebrae using screws. Stability enhancement is possible by means of interconnection mechanisms and transverse connectors used as cross connectors.

The M.U.S.T. MINI Posterior Cervical Screws System is intended to stabilize and fuse the spine in degenerative disc disease, spinal fusion, cervical fractures, and in surgically repaired spinal pseudo-arthritis. In addition, the M.U.S.T. MINI Posterior Cervical Screws System is used in deformity correction e.g. scoliosis to correct and stabilize the spine.

The M.U.S.T. MINI Posterior Cervical Screws System consists of polyaxial screws (full and partially threaded), cannulated polyaxial screws (full and partially threaded), hooks, cross connectors, connectors and rods (straight and transition) are manufactured of Titanium-6Aluminum-4Vanadium Extra Low Interstitial (Ti-6Al-4V ELI). The M.U.S.T. MINI Posterior Cervical Screws System rods (straight and transition) are manufactured of Cobalt-Chromium-Molybdenum Alloy.

The M.U.S.T. MINI Posterior Cervical Screws System is similar to competitor predicate devices Synthes' Axon System (K991089 and K023675), Synthes' Synapse System (K070573 and K142838) and Medtronic's Vertex System (K123906).

#### **V. Indications for Use**

The M.U.S.T. MINI Posterior Cervical Screws System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1 to T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g., pseudarthrosis); tumors involving the cervical spine; degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The

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M.U.S.T. MINI Posterior Cervical Screws System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

In order to achieve additional levels of fixation, the M.U.S.T. MINI Posterior Cervical Screws System may be connected to the M.U.S.T. System Rods with the M.U.S.T. MINI Rod Connectors. Transition rods with differing diameters may also be used to connect the M.U.S.T. MINI Posterior Cervical Screws System to the M.U.S.T. System. Refer to the M.U.S.T. System package insert for a list of the M.U.S.T. indications of use.

## **VI. Comparison of Technological Characteristics**

The M.U.S.T. MINI Posterior Cervical Screws System and the predicate devices share the following characteristics:

- indications for use;
- material;
  - The materials for the Rods, Connectors, and Hooks are made of the similar materials of titanium alloy and CoCrMo. The Polyaxial Screws are made of titanium alloy Eli versus the predicate which are made of titanium aluminum niobium.
- screw diameters;
- screw driving interface;
- rod diameters;
- rod straight lengths;
- connector designs;
- hook designs;
- hook sizes;
- sterile;
- device usage.

The M.U.S.T. MINI Posterior Cervical Screws System is technologically different from the predicate devices as follows:

- polyaxial screw lengths;
- polyaxial angulation;
- rod tapered lengths.

The M.U.S.T. MINI Posterior Cervical Screws System components are manufactured from Titanium-6Aluminum-4Vanadium Extra Low Interstitial Alloy (ISO 5832-3:1996 Implants For Surgery – Metallic Materials – Part 3: Wrought Titanium-6Aluminum-4Vanadium Alloy and ASTM F136-13 Standard Specification For Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy For Surgical Implant Applications) and/or Cobalt-Chromium-Molybdenum Alloy (Co-Cr-Mo) (ISO 5832-12 Second Edition 2007-05-01: Implants For Surgery-- Metallic Materials -- Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy

[Including: Technical Corrigendum 1 (2008)] and ASTM F1537-11 Standard Specification for Wrought Cobalt-28Chromium-6-Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538 and UNS R31539)).

The polyaxial screws, hooks, lateral connector, rod to rod connector, cross connector clamp and spinous reconstruction cross connectors are Type III color anodized.

These materials have a long history of use in implantable orthopedic devices and material information has been provided in the listed predicate devices' 510(k) submissions; Synthes' Axon System (K991089 and K023675), Synthes' Synapse System (K070573 and K142838) and Medtronic's Vertex System (K123906).

A comparison of the subject and predicate devices are provided in the tables below.

Technological comparison

<b>Parameters</b>	<b>M.U.S.T. MINI Posterior Cervical Screws System: Polyaxial Screws (Subject Device)</b>	<b>Synthes Synapse Systems K070573 and K142838 (Predicate Device)</b>	<b>Synthes Cervifix/Axon Systems K991089 and K023675 (Predicate Device)</b>	<b>Medtronic Vertex Reconstruction System K123906 (Predicate Device)</b>
<b>Material</b>	Titanium Alloy (ELI)	Titanium Aluminum Niobium	Titanium Aluminum Niobium	Titanium Aluminum Niobium, Nitinol
<b>Screw Diameter</b>	3.5 mm, 4.0 mm, 4.5 mm	3.5 mm, 4.0 mm, 4.5 mm	3.5 mm, 4.0 mm	3.5 mm, 4.0 mm, 4.5 mm
<b>Length</b>	Ø 3.5 mm and Ø 4.0 mm: 10 to 40 mm (Full Thread) Ø 4.0 mm and Ø 4.5 mm: 26 to 42 mm (Partial Thread) Ø 4.5 mm: 26 to 50 mm (Full Thread)	Cancellous: 8-50 mm Smooth shaft (10 mm w/o thread): 18-50 mm	Cancellous: 8-26 mm Cortex: 28-50 mm	Ø 3.5 mm: 10-40 mm (Full Thread) Ø 4.0 mm and Ø 4.5 mm: 10-52 mm (Full Thread) Ø 3.5 mm and Ø 4.0 mm: 18-40 mm (Partial Thread)
<b>Device Usage</b>	Single Use	Single Use	Single Use	Single Use
<b>Biocompatibility</b>	Implant with permanent >30 day	Implant with permanent >30 day	Implant with permanent >30 day	Implant with permanent >30 day
<b>Sterilization</b>	Yes	Yes	Yes	Sterile/Non-Sterile

<b>Parameters</b>	<b>M.U.S.T. MINI Posterior Cervical Screws System: Rods (Subject Device)</b>	<b>Synthes Synapse Systems K070573 and K142838 (Predicate Device)</b>	<b>Synthes Cervifix/Axon Systems K991089 and K023675 (Predicate Device)</b>
<b>Material</b>	Titanium Alloy (ELI) and CoCrMo	Titanium Aluminum Niobium	Titanium Alloy (TAN) and Commercial Pure Titanium
<b>Diameter</b>	Straight: Ø 3.5 mm Tapered: Ø 3.5/5.5 mm	Straight: Ø 3.5 mm Tapered: Ø 3.5/5.0 mm, Ø 3.5/6.0 mm, Ø 4.0/5.0 mm and Ø 4.0/6.0 mm	Straight: Ø 3.5 mm Tapered: Ø 3.5/5.0 mm and Ø 3.5/6.0 mm
<b>Length</b>	Straight: 80 mm, 120 mm, 240 mm, 350 mm Tapered: 180 mm, 360 mm, 420 mm, 600 mm	Straight: 80 mm, 120 mm, 240 mm, 350 mm Tapered: 40 mm, 80 mm	Straight: 80 mm, 120 mm, 240 mm Tapered: 120/170 mm, 240/250 mm, 190/500 mm
<b>Device Usage</b>	Single Use	Single Use	Single Use
<b>Biocompatibility</b>	Implant with permanent >30 day	Implant with permanent >30 day	Implant with permanent >30 day
<b>Sterilization</b>	Sterile	Sterile	Sterile

<b>Parameters</b>	<b>M.U.S.T. MINI Posterior Cervical Screws System: Connectors (Subject Device)</b>	<b>Synthes Synapse Systems K070573 and K142838 (Predicate Device)</b>	<b>Synthes Cervifix/Axon Systems K991089 and K023675 (Predicate Device)</b>
<b>Material</b>	Titanium Alloy (ELI)	Titanium Alloy (ELI)	Titanium Alloy (ELI)
<b>Lateral Connector</b>	Diameter: Ø 3.5 mm Length: 10 mm and 15 mm	Diameter: Ø 3.5 mm and Ø 4.0 mm Length: Unknown	Diameter: Ø 3.5 mm Length: Unknown
<b>Rod to Rod Connector</b>	Diameter: Ø 3.5 to Ø 5.5 mm	Diameter: Ø 3.5 to Ø 3.5 mm Ø 3.5 to Ø 4.0 mm Ø 3.5 to Ø 5.0 mm Ø 3.5 to Ø 6.0 mm	Diameter: Ø 3.5 to Ø 3.5 mm Ø 3.5 to Ø 5.0 mm Ø 3.5 to Ø 6.0 mm
<b>Standard Cross Connector</b>	Adjustable Length: 15 to 70 mm	Adjustable Length: 60 to 75 mm	Length: 60 mm and 75 mm
<b>Screw to Screw Cross Connector</b>	Distance: 22-30 mm, 29-37 mm, 36-44 mm, 43-51 mm, 50-58 mm	Distance: 4 adjustable sizes (specific distance unknown)	N/A
<b>Device Usage</b>	Single Use	Single Use	Single Use



<b>Parameters</b>	<b>M.U.S.T. MINI Posterior Cervical Screws System: Connectors (Subject Device)</b>	<b>Synthes Synapse Systems K070573 and K142838 (Predicate Device)</b>	<b>Synthes Cervifix/Axon Systems K991089 and K023675 (Predicate Device)</b>
<b>Biocompatibility</b>	Implant with permanent >30 day	Implant with permanent >30 day	Implant with permanent >30 day
<b>Sterilization</b>	Sterile	Sterile	Sterile

<b>Parameters</b>	<b>M.U.S.T. MINI Posterior Cervical Screws System (Subject Device)</b>	<b>Synthes Synapse Systems K070573 and K142838 (Predicate Device)</b>
<b>Material</b>	Titanium Alloy (ELI)	Titanium Alloy (ELI)
<b>Types</b>	Straight, Angled (right/left), and Offset (right/left)	Straight, Angled (right/left), and Offset (right/left)
<b>Size</b>	Small (4.5 mm) and Large (6.0 mm)	Small (4.5 mm) and Large (6.0 mm)
<b>Device Usage</b>	Single Use	Single Use
<b>Biocompatibility</b>	Implant with permanent >30 day	Implant with permanent >30 day
<b>Sterilization</b>	Sterile	Sterile

*Discussion*

As seen above, the technological differences between the subject and predicate devices do not raise new questions of safety and/or effectiveness. The M.U.S.T. MINI Posterior Cervical Screws System is the same or similar to the predicate devices in terms of intended use, materials of construction, design, size, diameter, device usage, and sterility. Based on the comparison of technological characteristics and performance data provided within this submission, the data supports the substantial equivalence of the M.U.S.T. MINI Posterior Cervical Screws System to the identified predicate devices.

## VII. Performance Data

The following mechanical tests are being provided in support of a substantial equivalence determination. Based on the risk analysis, testing was conducted to written protocols with acceptance criteria that were based on standards and FDA guidance document “FDA Guidance for Industry and FDA Staff, Spinal System 510(k)s”.

### Non-Clinical Studies

- Mechanical Tests
  - Static and dynamic compression
    - Per ASTM F1717-15 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
  - Static and dynamic torsion
    - Per ASTM F1717-15 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model
  - Static axial and torsional grip
    - Per ASTM F1798-13 Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
  - A-P screw pull out
    - Per ASTM F1798-13 Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
  - Flexion-extension
    - Per ASTM F1798-13 Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants
  - Torque to failure
- Cadaver Testing
- Design Comparisons
- Pyrogenicity
  - The Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and the Pyrogen Test according to USP chapter <151> for pyrogenicity determination.
  - The subject devices are not labeled as non-pyrogenic or pyrogen free.

### Clinical Studies

- No clinical studies were conducted.

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**VIII. Conclusion**

The information provided above supports that the M.U.S.T. MINI Posterior Cervical Screws System is as safe and effective as the predicate devices. Therefore, it is concluded that the M.U.S.T. MINI Posterior Cervical Screws System is substantially equivalent to the predicate devices.

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