2.0 510(k) Summary

I. Submitter

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

Contact Person: Stefano Baj, Regulatory Affairs Manager, Medacta International SA
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II. Device

Device Proprietary Name:	M.U.S.T. MINI Posterior Cervical Screws System
Common or Usual Name:	Spinal Interlaminal Fixation Orthosis
Classification Name:	Appliance, Fixation, Spinal Interlaminal
Primary Product Code:	NKG
Secondary Product Code:	KWP
Regulation Number:	Unclassified
Secondary Regulation Number:	21 CFR 888.3050
Device Classification	Unclassified

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:
- M.U.S.T. MINI Posterior Cervical Screws System, K171369, Medacta International SA

Additional predicate devices:
- Certex OCT Spinal Implant System, K133094, X-Spine Systems, Inc.
- Certex Spinal Fixation System, K160428, X-Spine Systems, Inc.

IV. Device Description

The M.U.S.T. MINI Posterior Cervical Screws System straight rods (Ø3.5) are a line extension to the previously cleared Medacta M.U.S.T. MINI Posterior Cervical Screws System (K171369) and are provided in multiple lengths (30 – 115 mm in 5 mm increments).

The M.U.S.T. MINI Posterior Cervical Screws System straight rods are manufactured from Ti-6Al-4V ELI (*ISO 5832-3 Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy + ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*) and CoCrMo (*ISO 5832-12 Implants for surgery -- Metallic materials -- Part 12: Wrought cobalt-chromium-molybdenum alloy + ASTM F1537 Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)*).

V. Indications for Use

The M.U.S.T. MINI Posterior Cervical Screw System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion, in skeletally mature patient, 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 Screw 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 Screw 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 Screw 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.

When used with the Occipital Plate, the M.U.S.T MINI Posterior Cervical Screw System is also intended to provide immobilization and stabilization for the occipito-cervico-thoracic junction (occiput – T3) in treatment of the instabilities mentioned above, including occipitocervical dislocation.

VI. Comparison of Technological Characteristics

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

- diameter and length;
- materials of construction;
- biocompatibility;
- device usage;
- sterility;

- shelf life; and
- packaging.

The subject devices are substantially equivalent to the primary predicate device M.U.S.T. MINI Posterior Cervical Screws System (K171369) and have been designed with the same lengths as the previously cleared Certex OCT Spinal Fixation System (K133094 and K160428).

VII. Performance Data

- Engineering Rationale

  A comparative analysis of the subject devices to the primary predicate device was performed to determine if the shorter length rods created a new worst-case product size. It was determined that the subject rods are equivalent to the previously cleared longer rods in terms of mechanical strength as there is no change to the rod diameter or materials.
  Therefore, no additional mechanical testing were performed; no design validation was undertaken.

VIII. Conclusion

The information provided above supports that the M.U.S.T. MINI Posterior Cervical Screws System straight rods are as safe and effective as the predicate devices. Although minor differences in length exist between the subject and primary predicate device, testing supports that these differences do not raise any new questions of safety or effectiveness. Therefore, it is concluded that the M.U.S.T. MINI Posterior Cervical Screws System straight rods are substantially equivalent to the identified predicate devices.