DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K190631

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

Indications for Use *(Describe)*

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.

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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