K965145
1 of 2

MAR 13 1997

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988
510(K) CONTACT:	Cheryl Hastings Manager, Clinical Affairs
TRADE NAME:	DePuy Motech MOSS Miami Spinal System
COMMON NAME:	Hook, rod and screw spinal instrumentation
CLASSIFICATION:	888.3050 Spinal interlaminal fixation orthosis
DEVICE PRODUCT CODES:	87 KWQ, KWP, MNH
SUBSTANTIALLY EQUIVALENT DEVICES:	⇨ DePuy Motech MOSS Miami Spinal System ⇨ DePuy Motech MOSS Miami Spinal System,Pedicle Fixation ⇨ DePuy Motech MOSS Miami Spinal System - Anterior Use

DEVICE DESCRIPTION AND INTENDED USE:
The MOSS MIAMI Spinal System is available in either Stainless Steel or Titanium. The following components are currently available in Stainless Steel: 5mm diameter longitudinal rods, 5-7mm diameter monoaxial screws, 5-7mm diameter polyaxial screws, hooks, transverse connectors, axial connectors and staple washers. The following components are currently available in Titanium: 5.5mm diameter longitudinal rods, 5-8mm diameter monoaxial screws, 5-7mm diameter polyaxial screws, hooks, transverse connectors, axial connectors, washers and staple washers.

This submission describes the addition of 5mm x 12cm, 5mm x 30cm and 5mm x 48cm longitudinal ratchet rods to the Stainless Steel MOSS Miami Spinal System. The ratchet rods are similar to the MOSS Miami 5.0mm smooth longitudinal rods that have been previously cleared for anterior, posterior non-pedicle use and posterior pedicle fixation (Grades III or IV spondylolisthesis at L5-S1). The ratchet rods are manufactured from the same material and have the same lengths as the previously cleared, smooth, longitudinal rods. The only difference in design between the subject ratchet rods and the previously cleared, smooth, longitudinal rods is that the ratchet rods are cold-worked, creating a ringed outer surface.

The ratchet rod system was designed to make interoperative adjustments of components easier and quicker than with the smooth rod system. When the ratchet rods are used, hooks and screws can be initially positioned on the rod and held in place with a loose connection, then ratcheted into final position and tightened. With the smooth rods, components are tightened onto the rod and then must be repeatedly loosened, moved and re-tightened until final positioning is accomplished.

K965145
2 of 2

The 5mm ratchet rods described in this submission are intended to be used with the existing MOSS Miami Stainless Steel hooks, screws, inner screw and outer locking nut which have previously been cleared for marketing.

The MOSS Miami Spinal System, with either the existing smooth rods or the subject ratchet rods, is intended for non-cervical use in the spine. When used with anterior screw fixation or posterior hook, non-pedicle screw fixation the MOSS Miami Spinal System is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed back surgery or degenerative disc disease (i.e. discogenic back pain with degeneration of the disc confirmed by history and radiographic studies).

When used with pedicle screw fixation, the MOSS Miami Spinal System is intended for use in patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 and below), and for whom the device system is intended to be removed after the development of a solid fusion mass.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The MOSS Miami 5mm Ratchet Rod is substantially equivalent to the MOSS Miami 5mm smooth rod that has been previously cleared for posterior non-pedicle use, limited posterior pedicle fixation and anterior use. This substantial equivalence is based on similar designs, similar interconnection mechanisms, identical materials, comparable static and fatigue strength and identical indications for use.