K964024

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510(k) SUMMARY

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:	Rod and screw spinal instrumentation
CLASSIFICATION:	888.3050 Spinal interlaminal fixation orthosis
DEVICE PRODUCT CODE:	87 KWP, KWQ and MNH
SUBSTANTIALLY EQUIVALENT DEVICES:	▷ DePuy Motech MOSS Miami Spinal System - Titanium Components ▷ DePuy Motech MOSS Miami Spinal System - Anterior Use

INTENDED USE AND DEVICE DESCRIPTION:
The MOSS Miami Spinal System 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 attachment are L3 and below), and for whom the device system is intended to be removed after the development of a solid fusion mass.

The MOSS MIAMI System is available in either Stainless Steel or Titanium. The following components are available in Stainless Steel: 4mm and 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 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.

Titanium components of the MOSS Miami Spinal System were cleared in K955348 for the intended uses listed above. The components that were cleared included 5.5mm longitudinal smooth rods, 6 and 7mm diameter mono- and polyaxial screws, inner screws, outer locking nuts, washers, staple washers, hooks, transverse connectors and axial connectors. Additional screws with diameters of 5mm and 8mm are now being added to this system. These additional components are intended to be used with the Titanium

MOSS Miami rods, hooks, screws, transverse and axial connectors and outer locking nut which have previously been described and cleared for marketing in K955348.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The 5 and 8mm diameter Titanium MOSS Miami screws are substantially equivalent to the screws originally cleared in K955348 (6 and 7mm diameter) in that they are manufactured from the same material, have the same intended use and have basically the same design. The only differences between the screws previously cleared and the screws that are the subject of this submission are that the 5mm screws have slightly shorter threads than the 6mm screws (but the same minor diameter) and the 8mm screws have a slightly larger diameter than the 7mm screws. The 5mm Titanium screws have the same design as the 5mm Stainless Steel screws that were cleared in K953915.