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MAR 18 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:	Rod and screw spinal instrumentation
CLASSIFICATION:	888.3050 Spinal interlaminal fixation orthosis
DEVICE PRODUCT CODE:	Product code: 87 KWP
SUBSTANTIALLY EQUIVALENT DEVICES:	▷ DePuy Motech MOSS Spinal System ▷ DePuy Motech MOSS Miami Spinal System, Pedicle Fixation ▷ DePuy Motech MOSS Spinal System, Pedicle Fixation

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.

The products covered in this submission are additional components to the existing MOSS Miami Spinal System and consist of: 4mm x 48cm longitudinal rods and 6mm monoaxial screws available in lengths from 25mm-55mm. All of these components are manufactured from Stainless Steel. The 6mm monoaxial screws are identical to those cleared in previous 510(k) submissions except the slot in the head is narrowed to accommodate a 4mm rod. The inner screws and outer locking nuts used to fix the monoaxial screws to the 4mm rod have also been cleared in previous 510(k) submissions.

Aside from the screws and outer locking nuts, the 4mm components described in this submission cannot be used interchangeably with the MOSS Miami 5mm rods, screws and hooks designed for use with that system.

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).

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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.