5. 510(K) SUMMARY – K070300

5.1. 510(k) Summary – EXPEDIUM 5.5mm / 6.35mm Spine Systems

Submitter: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

APR 10 2007

Contact Person: Christopher Klaczyk
Regulatory Affairs Project Manager
Voice: (508) 828-2852
Fax: (508) 828-3797
E-Mail: cklaczyk@dpyus.jnj.com

Date Prepared: January 30, 2007

Device Class: Class III

Classification Name: Pedicle screw spinal fixation (§888.3070)

Classification Panel: Orthopedics

FDA Panel Number: 87

Product Code(s): KWP, KWQ, MNH, MNI, NKB

Proprietary Name: EXPEDIUM SFX Cross Connector System

Predicate Devices: DePuy Motech MOSS MIAMI Spinal System (K933881), SFX Snap-Fit Cross Connector System (K062196)

Device Description: The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 5.5mm and 6.35mm spinal rods of the EXPEDIUM Spine System.

Intended Use: The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available EXPEDIUM 5.5mm and 6.35mm Spine Systems.

Page 1 of 2

K070300

The uses of the legally marketed EXPEDIUM 5.5mm and 6.35mm Spine System are as follows:

The EXPEDIUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Materials: Manufactured from ASTM F 138 implant grade stainless steel.

Performance Data: Performance data per ASTM F 1717 were submitted to characterize the subject EXPEDIUM™ Spine System components addressed in this notification.

K070300

5.2. 510(k) Summary – VSP 6.35mm Spine System

Submitter: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person: Christopher Klaczyk
Regulatory Affairs Project Manager
Voice: (508) 828-2852
Fax: (508) 828-3797
E-Mail: cklaczyk@dpyus.jnj.com

Date Prepared: January 30, 2007

Device Class: Class II

Classification Name: Spinal interlaminar fixation orthosis, §888.3050
Pedicle screw spinal fixation, §888.3070

Classification Panel: Orthopedics

FDA Panel Number: 87

Product Code(s): KWP, MNH, MNI

Proprietary Name: EXPEDIUM SFX Cross Connector System

Predicate Devices: DePuy Motech MOSS MIAMI Spinal System (K933881), SFX Snap-Fit Cross Connector System (K062196)

Device Description: The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 6.35mm spinal rods of the VSP Spine System.

Intended Use: The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available VSP 6.35mm Spine System.

Page 1 of 7

The uses of the legally marketed VSP 6.35mm Spine System are as follows:

The VSP System is indicated for degenerative spondylolisthesis, in skeletally mature patients, with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The VSP Spine System is also indicated for pedicle screw fixation for severe spondylolisthesis (Grade 3 and 4) at L5-S1, in skeletally mature patients, when autogeous bone graft is used, when affixed to the posterior lumbosacral spin, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

Materials: Manufactured from ASTM F 138 implant grade stainless steel.

Performance Data: Performance data per ASTM F 1717 were submitted to characterize the subject EXPEDIUM™ Spine System components addressed in this notification.

K070300

5.3. 510(k) Summary – ISOLA 6.35mm Spine System

Submitter: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person: Christopher Klaczyk
Regulatory Affairs Project Manager
Voice: (508) 828-2852
Fax: (508) 828-3797
E-Mail: cklaczyk@dpyus.jnj.com

Date Prepared: January 30, 2007

Device Class: Class II

Classification Name: Spinal interlaminar fixation orthosis, §888.3050
Pedicle screw spinal fixation, §888.3070

Classification Panel: Orthopedics

FDA Panel Number: 87

Product Code(s): KWP, MNH, MNI

Proprietary Name: EXPEDIUM SFX Cross Connector System

Predicate Devices: DePuy Motech MOSS MIAMI Spinal System (K933881), SFX Snap-Fit Cross Connector System (K062196)

Device Description: The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 6.35mm spinal rods of the ISOLA Spine System.

Intended Use: The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available ISOLA 6.35mm Spine System.

page 1 of 7

K070300

The uses of the legally marketed ISOLA 6.35mm Spine System are as follows:

The ISOLA Spine Systems is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The ISOLA Spine Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The ISOLA Spine Systems is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The ISOLA Spinal System when used with pedicle screws is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

Materials: Manufactured from ASTM F 138 implant grade stainless steel.

Performance Data: Performance data per ASTM F 1717 were submitted to characterize the subject EXPEDIUM™ Spine System components addressed in this notification.

pg 2 of 2

K070300

5.4. 510(k) Summary – MOSS Miami 6.35mm Spine System

Submitter: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

Contact Person: Christopher Klaczyk
Regulatory Affairs Project Manager
Voice: (508) 828-2852
Fax: (508) 828-3797
E-Mail: cklaczyk@dpyus.jnj.com

Date Prepared: January 30, 2007

Device Class: Class II

Classification Name: Spinal interlaminar fixation orthosis, §888.3050
Pedicle screw spinal fixation, §888.3070

Classification Panel: Orthopedics

FDA Panel Number: 87

Product Code(s): KWP, MNH, MNI

Proprietary Name: EXPEDIUM SFX Cross Connector System

Predicate Devices: DePuy Motech MOSS MIAMI Spinal System (K933881), SFX Snap-Fit Cross Connector System (K062196)

Device Description: The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The connector minimizes the torsional forces on the construct, thus reducing the micromotion and the probability of the construct shifting after placement. It is designed to accommodate the 6.35mm spinal rods of the MOSS Miami Spine System.

Intended Use: The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available MOSS Miami 6.35mm Spine System.

The uses of the legally marketed MOSS Miami 6.35mm Spine System are as follows:

When used as a posterior, noncervical hook, and/or sacral/iliac screw fixation system, or as an anterior, thoracic/lumbar screw fixation system, the MOSS Miami 6.35mm Spinal System is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the MOSS Miami 6.35mm Spinal System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

The MOSS Miami 6.35mm Spine Systems is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of 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-S1) and for whom the device system is intended to be removed after solid fusion is attained.

Materials: Manufactured from ASTM F 138 implant grade stainless steel.

Performance Data: Performance data per ASTM F 1717 were submitted to characterize the subject EXPEDIUM™ Spine System components addressed in this notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Spine, Inc.
% Mr. Christopher Klaczyk
Regulatory Affairs Project Manager
325 Paramount Drive
Raynham, Massachusetts 02767

APR 10 2007

Re: K070300
Trade/Device Name: EXPEDIUM™ SFX Cross Connector System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: March 9, 2007
Received: March 12, 2007

Dear Mr. Klaczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Brehm

for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

K070300

4. INDICATIONS FOR USE STATEMENT

4.1. Indications for Use – EXPEDIUM™ 5.5mm / 6.35mm Spine Systems

510(k) Number (if known):

Device Name: EXPEDIUM™ SFX Cross Connector System

Indications For Use:

The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available EXPEDIUM 5.5mm and 6.35mm Spine Systems.

The uses of the legally marketed EXPEDIUM 5.5mm and 6.35mm Spine System are as follows:

The EXPEDIUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K070300

K070300

4.2. Indications for Use – VSP® Spine System

510(k) Number (if known):

Device Name: EXPEDIUM™ SFX Cross Connector System

Indications For Use:

The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available VSP Spine System.

The uses of the legally marketed VSP Spine System are as follows:

The VSP System is indicated for degenerative spondylolisthesis, in skeletally mature patients, with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The VSP Spine System is also indicated for pedicle screw fixation for severe spondylolisthesis (Grade 3 and 4) at L5-S1, in skeletally mature patients, when autogeous bone graft is used, when affixed to the posterior lumbosacral spin, and intended to be removed after solid fusion is attained. Levels of fixation are from L3-S1.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buell MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K070300

K070300

4.3. Indications for Use – ISOLA® 6.35mm Spine System

510(k) Number (if known):

Device Name: EXPEDIUM™ SFX Cross Connector System

Indications For Use:

The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available ISOLA 6.35mm Spine System.

The uses of the legally marketed ISOLA 6.35mm Spine System are as follows:

The ISOLA Spine Systems is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The ISOLA Spine Systems is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The ISOLA Spine Systems is also a hook and sacral/iliac screw fixation system of the noncervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudarthrosis).

The ISOLA Spinal System when used with pedicle screws is indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___ ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buenn

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

page 1 of 1

510(k) Number K070300

K070300

4.4. Indications for Use – MOSS® Miami 6.35mm Spine System

510(k) Number (if known):

Device Name: EXPEDIUM™ SFX Cross Connector System

Indications For Use:

The EXPEDIUM SFX Cross Connector System is designed to transversely connect two rods used in spinal instrumentation constructs. The EXPEDIUM SFX Cross Connector System devices are intended for use with components of the commercially available MOSS Miami 6.35mm Spine System.

The uses of the legally marketed MOSS Miami 6.35mm Spine System are as follows:

When used as a posterior, noncervical hook, and/or sacral/iliac screw fixation system, or as an anterior, thoracic/lumbar screw fixation system, the MOSS Miami 6.35mm Spinal System is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e., discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the MOSS Miami 6.35mm Spinal System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

The MOSS Miami 6.35mm Spine Systems is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of 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-S1) and for whom the device system is intended to be removed after solid fusion is attained.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___ ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buch MD

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of 1

510(k) Number K070300