K071857
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## 510(k) SUMMARY

**K071857** - 510 (K) Premarket Notification

AUG - 8 2007

**Jemo Spine, LLC, *DELTA*™, Spinal Fusion System**

**1. Submitter/Sponsor:**
Jemo Spine, LLC,
6170 South 380 west Suite 200.
Murray, Utah. 84107
**Contact person:**
Patrick Moore
Vice-President , Jemo Spine, LLC.
Tel: 801-266-4811; Fax: 801-255-4363
**Date Prepared:**
July 30th, 2007

**2. Device Name:**
Proprietary/Trade Name: Jemo Spine, LLC, *DELTA*™, Spinal Fusion System
Common/Usual Name: Pedicle Screw Spinal System
Classification Name: Pedicle Screw Spinal System

**3. Device Classification(s):**
Class II (88.3390) following Orthopedic and Rehabilitation Device Advisory Review, for the requested indications:

- Spinal Pedicle Screw (MNI) 21 CFR § 888.3070
- Spondylolisthesis Spinal Fixation Device System (MNH) 21 CFR § 888.3070
- Spinal Intervertebral Body Fixation Orthosis (KWQ) 21 CFR § 888.3060

**4. Predicate Device:**
U&I Corporation, *OPTIMA*™ Spinal System -- MNH, MNI, KWQ -- (K020279 and K024096)

**5. Device Description:**
The Jemo Spine, LLC, *DELTA*™, Spinal Fusion System is a top-loading posterior spinal fixation system which consists of pedicle screws, rods, cap/set screws, and a transverse (cross) linking mechanism. The Jemo Spine, LLC, *DELTA*™, Spinal Fusion System implant components are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available.

The Jemo Spine, LLC, *DELTA*™, Spinal Fusion System can be used in the posterior plane providing unilateral and bilateral modes of fixation.

The Jemo Spine, LLC, *DELTA*™, Spinal Fusion System design allows adjustment in both the sagittal and coronal planes permitting screw placement according to the best possible anatomic (spinal) location and orientation.
This is accomplished by means of a preassembled bi-polar cup and internal saddle in the housing component between the screw and the rod which tightens against the head

of the pedicle screw upon interface of the cap/set screw assembly with the rod.

Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the Jemo Spine, LLC, *DELTA™*, Spinal Fusion System implants.

From the foregoing, we conclude that the subject Jemo Spine, LLC, *DELTA™*, Spinal Fusion System device is as safe and effective as named predicate and currently marketed competitive devices for the stated indications.

**6. Indications for Use:**
The Jemo Spine, LLC, *DELTA™*, Spinal Fusion System, a posterior spinal fixation device is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 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.

In addition, the Jemo Spine, LLC, *DELTA™*, Spinal Fusion System is 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).

When used as an posterior screw fixation system such as a sacral/iliac screw fixation system, the Jemo Spine, LLC, *DELTA™*, Spinal Fusion System is indicated for patients with severe Spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthrosis, or revision of failed fusion attempts.

**7. Comparison with predicate device:** Jemo Spine, LLC, *DELTA™*, Spinal Fusion System is substantially equivalent to the currently marketed *OPTIMA™* Spinal System

When considered for anterior applications, both the *DELTA™ Spinal Fusion System* and the *OPTIMA™* Spinal System worst case constructs consist of a universal housing containing a pre-assembled pedicle screw and set screw; (*DELTA™*, Spinal Fusion System employs a proximal-cap/set-screw assembily). Both systems use a vertical rods (*DELTA™ Spinal Fusion System* uses a 5.5mm rod and the *OPTIMA™* Spinal System uses 6.0mm diameter rod) which are both placed into the housing. The proximal cap/set screw assembly for the *DELTA™ Spinal Fusion System and only a set screw with* OPTIMA™ Spinal System are subsequently tightened onto the rod, providing a completed implant assembly.

The principles of operation for the subject JEMO SPINE, LLC. *DELTA™ Spinal Fusion System* device, and the cited predicate technologies are similar. That is, each of these products employs similar indications for use, contraindications for use, warnings and precautions within labeling. The principles of operation of the subject device are directly equivalent to those of the cited predicates cleared by the Agency and currently being marketed.

The target populations on which product usage would occur for the subject device shall

remain similar / equivalent to those of the cited predicate products.

A properly placed pedicle is fully seated against the vertebral body, rendering the largest prominence the housing / seated set screw. The largest width is the largest diameter of the housing component.

Matrix 1

| Component(s) | Dimension | Delta™ | Optima™ |
|---|---|---|---|
| Universal Housing | Height | 0.670" | 0.680" |
| Universal Housing | O.D. / Implant Width | 0.540" | 0.550" |
| Pedicle Screw / Housing / Rod / Set Screw | Implant Height / Prominence | 0.690" | 0.690" |

As shown in the above matrix 1, the height and width in the Optima™ is ~0.010" larger than in the *DELTA™* Spinal Fusion System; in side by side comparison, the Overall prominence height in the Optima™ is equal to the *DELTA™* Spinal Fusion System.

(The term "substantial Equivalence" is used only as it is defined in the Medical Device Amendment of 1976 as amended by the Safe Medical Device Act of 1990 and is not intended to, nor does it refer to, the definition of substantial equivalence in the U.S. or any other patent law.)

The design and development process of the manufacturer of subject system and Predicate system conforms to 21 CFR part 820, ISO 9001 and ISO 13485 quality systems.

Both the subject device and the predicate device were evaluated/tested per established requirements. The mechanical testing included static and fatigue testing performed per ASTM F 1717-04.

Clinical tests: No clinical tests conducted on either the subject system nor the predicate system.

Conclusion: The subject device was evaluated against the predicate device for all performance, safety & effectiveness requirements and found as substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2007

Jemo Spine, LLC
% Mr. Patrick Moore
Vice President
6170 South 380 West Suite 200
Murray, Utah 84107

Re: K071857
Trade/Device Name: Jemo Spine DELTA™ Spinal Fusion System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWQ
Dated: June 27, 2007
Received: July 5, 2007

Dear Mr. Moore:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the 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

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SECTION II

INDICATIONS for USE STATEMENT

**510(k) Number (if known):** K071857

**Device Name:** Jemo Spine, LLC, *DELTA*™, Spinal Fusion System.

**Indications for Use:** The Jemo Spine, LLC, *DELTA*™, Spinal Fusion System, a posterior spinal fixation device is a pedicle screw system indicated for the treatment of severe Spondylolisthesis (Grade 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.

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**Prescription Use_____X_____ OR Over-the-Counter Use_____(Per 21 CFR 801.109)**
**(Optional Format 1-2-96)**

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

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**

Barbara Buchman

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

**510(k) Number** K071857