510(k) Summary of Safety and Effectiveness
for the
Phantom™ Plus Cage System
510(k) Number : K082801

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
The following 510(k) summary is submitted for the Phantom™ Plus Cage System.

DEC 22 2008

1. Submitter :
US Spine, Inc.
3600 FAU Blvd, Suite 101
Boca Raton, FL 33431

Contact Person :
Peter Harris
US Spine, Inc.
3600 FAU Blvd, Suite 101
Boca Raton, FL 33431
Telephone: 561-367-7463

Date Prepared: September 22, 2008

2. Tradename: Phantom™ Plus Cage System
Common Name: Intervertebral Body Fusion Device
Classification Name: Intervertebral Body Fusion Device- Lumbar
Intervertebral Body Fusion Device- Cervical
21 CFR §888.3080
MAX/ODP
Class II

3. Predicate or legally marketed device(s) which are substantially equivalent:

- BAK™ Interbody Fusion System, BP/Lordotic Device: Sulzer Spine-Tech (P950002)
- LUMBAR I/F Cage® System: Depuy Acromed (P960025)
- PATRIOT™ Spacers: Globus Medical (K072970)
- SHELL/WAVE/LOOP Cages: Advanced Medical Technologies AG (K080401)

4. Description of the device:

The Phantom™ Plus Cage System consists of a variety of hollow vertebral body spacers featuring convex, bullet nose design and an axial void designed to hold bone graft material. The subject device is made of various lengths. The subject devices are designed with angular teeth to allow the implant to grip the superior and inferior end plates, thus allowing expulsion resistance. The devices range from 6mm to 22mm in height and 11mm to 45mm in length.

Materials: The devices are manufactured from Medical Grade PEEK (Polyetheretherketone) OPTIMA® LT1 (Invibio™) per ISO 10993-1 USP Class VI and ASTM F2026. Tantalum rods to be Grade UNS R05200 according to ASTM F560.

5. Intended Use:

The Phantom™ Plus Cages-Lumbar are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six (6) months of nonoperative therapy.

The Phantom™ Plus Cage System- Lumbar is to be filled with autogenous bone graft material. The Phantom™ Plus Cages- Lumbar are intended to be used with supplemental spinal fixation systems, such as Preference Pedicle Screw System.

Phantom™ Plus Cages-Cervical are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Phantom™ Plus Cages-Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone.

Phantom™ Plus Cages-Cervical are to used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

There are no significant differences between the Phantom™ Plus Cage System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

US Spine, Inc.
% Mr. Peter Harris
3600 FAU Boulevard, Suite 101
Boca Raton, Florida 33431

DEC 22 2008

Re: K082801
Trade/Device Name: Phantom™ Plus Cage System - Lunbar
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP, MAX
Dated: September 22, 2008
Received: September 24, 2008

Dear Mr. Harris:

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,

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

Enclosure

Indications for Use

510(k) Number: K082801

Device Name: Phantom™ Plus Cage System- Lumbar

Indications-For-Use:

The Phantom™ Plus Cages- Lumbar are intervertebral body fusion devices indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1.

DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade I spondylolisthesis at the involved level(s). These patients should be skeletally mature and have six (6) months of nonoperative therapy.

The Phantom™ Plus Cage System- Lumbar is to be filled with autogenous bone graft material. The Phantom™ Plus Cages- Lumbar are intended to be used with supplemental spinal fixation systems, such as Preference Pedicle Screw System.

Prescription use _X_ AND/OR Over-the-counter use _____
(Part 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM 12/22/2008

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

510(k) Number K082801

Indications for Use

510(k) Number: K082801

Device Name: Phantom™ Plus Cage System- Cervical

Indications-For-Use:

Phantom™ Plus Cages-Cervical are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level.

DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Phantom™ Plus Cages-Cervical are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone.

Phantom™ Plus Cages-Cervical are to used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription use _X_ AND/OR Over-the-counter use _____
(Part 21 CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM 12/22/2008

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

510(k) Number K082801

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