OCT 7 - 2005

510(K) Summary of Safety and Equivalency

Submitter:

Flexuspine, Inc.
120 W. Fifth Street
Suite 200
Tyler, TX 75701

Contact Person:

Corey Harbold
Vice President
Flexuspine, Inc.
120 W. Fifth Street
Suite 200
Tyler, TX 75701
Main: 1-888-692-0277
Fax: 903-596-8270
charbold@flexuspine.com

Date Prepared:

April 15, 2005

Trade Name:

EXPANSE Vertebral Body Replacement Device

Classification Name and Number:

Spinal Intervertebral body fixation orthosis
21 CFR 888.3060
Class II

Product Code:

MQP

Predicate Device(s):

The Flexuspine, Inc. Vertebral Body Replacement (VBR) Device is substantially equivalent to the TETRIS™ Spinal Implant, manufactured by Signus Medical LLC (K022793), the Theken CPOD/LPOD Vertebral Body Replacement System, manufactured by Theken Surgical (K032064), and the Spinal Concepts Inc. Coda®, manufactured by Spinal Concepts, Inc. (K033663).

Device Description:

The EXPANSE device is manufactured from implantable grade titanium 6Al-4V alloy that conforms to ASTM F-136. The device consists of opposing surfaces that make contact with the bony endplates of the vertebral bodies and can be expanded 2 mm in height. Following expansion, a shim is inserted between the opposing surfaces to provide mechanical integrity of the implanted device.

	Each surface in contact with the bony endplates is roughened to provide positive engagement with the endplates to resist rotation and migration. The EXPANSE is offered in five heights and a single length to provide the surgeon anatomic flexibility.
Intended Use:	Indications For Use: The EXPANSE Vertebral Body Replacement Device is indicated for use in the thoracolumbar spine (T3 – L5) to replace a collapsed, damaged or unstable vertebral body which has been resected or excised (i.e., partial or total vertebrectomy) due to tumor or trauma (i.e., fracture). EXPANSE VBR is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. EXPANSE VBR is intended to be used with bone graft and supplemental fixation. The supplemental internal fixation systems that may be used with the EXPANSE VBR Device include the Zodiac Polyaxial Pedicle Screw System, the Expedium Spinal System, the Expedium Anterior system, and the CD Horizon Spinal System, or equivalent systems. The EXPANSE VBR Device may be implanted singularly or in pairs.
Functional and Safety Testing:	Biocompatibility assessment and bench testing have been completed and support the safety and equivalency of the Flexuspine, Inc. Vertebral Body Replacement (VBR) Device.
Conclusion:	The Flexuspine, Inc. Vertebral Body Replacement (VBR) System is substantially equivalent in intended use, scientific technology, materials and design to predicate devices listed in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2005

Mr. Corey Harbold
Vice President
Flexuspine, Inc.
120 West Fifth Street, Suite 200
Tyler, Texas 75701

Re: K050997
Trade/Device Name: EXPANSE Spinal Vertebral Body Replacement Device (VBR)
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: MQP
Dated: September 13, 2005
Received: September 15, 2005

Dear Mr. Harbold:

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,

for Mark N. Melkerson,
Acting 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 (if known): TBD

Device Name: EXPANSE Vertebral Body Replacement Device

Indications For Use: The EXPANSE Vertebral Body Replacement (VBR) Device is indicated for use in the thoracolumbar spine (T3 - L5) to replace a collapsed, damaged or unstable vertebral body which has been resected or excised (i.e., partial or total vertebrectomy) due to tumor or trauma (i.e., fracture).

The EXPANSE VBR Device is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period. The EXPANSE VBR Device is intended to be used with bone graft and supplemental fixation. The supplemental internal fixation systems that may be used with the EXPANSE VBR Device include the Zodiac Polyaxial Pedicle Screw System, the Expedium Spinal System, the Expedium Anterior system, and the CD Horizon Spinal System, or equivalent systems.

The EXPANSE VBR Device may be implanted singularly or in pairs.

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)

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

510(k) Number K050997