K051060

1 of 2

MAY 19 2005

SPINAL CONCEPTS INC.
SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER:	Spinal Concepts, Inc. (an Abbott Laboratories Company)
ESTABLISHMENT REGISTRATION NUMBER:	1649384
CONTACT PERSON:	Noah Bartsch Specialist, Regulatory Affairs Telephone: 512.533.1840 Fax: 512.918.2784
DATE:	April 19, 2005
TRADE NAME:	Fortitude™ Vue Vertebral Body Replacement Device
PRODUCT CODE:	MQP
CLASSIFICATION NAME:	Spinal Vertebral Body Replacement Device
CLASSIFICATION REFERENCE:	21 CFR § 888.3060
PREDICATE DEVICE:	Fortitude™ Titanium manufactured by Spinal Concepts Inc., K031914, cleared August 12, 2003.
DEVICE DESCRIPTION:	Fortitude Vue is a hollow device intended for use as a spinal intervertebral body fixation orthosis.
INDICATIONS:	Fortitude Vue is a vertebral body replacement device that is intended for use in the thoracic and/or thoracolumbar spine (T3 - L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). Fortitude Vue 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. Fortitude Vue is intended to be used with bone graft.

COMPARISON TO PREDICATE DEVICE:

Fortitude Vue is substantially equivalent in design to the predicate device, and has the same intended use. The subject device is the result of a material change and minor design modifications to the predicate.

PERFORMANCE DATA (NONCLINICAL AND/OR CLINICAL):

NON-CLINICAL PERFORMANCE AND CONCLUSIONS:

Laboratory and bench testing results demonstrate that the proposed Fortitude Vue is substantially equivalent to the predicate device.

CLINICAL PERFORMANCE AND CONCLUSIONS:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2005

Mr. Noah Bartsch
Regulatory Affairs Specialist
Spinal Concepts Incorporated
5301 Riata Park Court, Bldg. F
Austin, Texas 78727

Re: K051000
Trade Name: Fortitude™ Vue VBR System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: April 19, 2005
Received: April 20, 2005

Dear Mr. Bartsch:

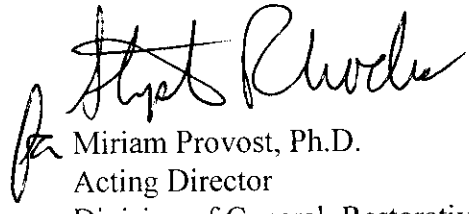
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



Miriam Provost, Ph.D.
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): K051000

Device Name:

Spinal Concepts Inc. Fortitude™ Vue Vertebral Body Replacement System

Indications for Use:

Fortitude Vue is a vertebral body replacement device that is intended for use in the thoracic and/or thoracolumbar spine (T3 - L5) to replace a collapsed, damaged or unstable vertebral body resected or excised (i.e., partial or total vertebrectomy procedures) due to tumor or trauma (i.e., fracture). Fortitude Vue 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. Fortitude Vue is intended to be used with bone graft.

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)

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

510(k) Number K051000