

JUL 24 2003

**Spinal Concepts, Inc.
Fortitude™ Cement Restrictor**

510(k) Summary**SUBMITTED BY**

Spinal Concepts, Inc.
5301 Riata Park Court, Bldg. F
Austin, TX 78727

**ESTABLISHMENT
REGISTRATION NUMBER**

1649384

CONTACT PERSONPrimary

Lisa Peterson
Regulatory Affairs Specialist

Alternate

David M. Hooper, Ph.D.
Director, Clinical and
Regulatory Affairs

Phone: 512-533-1080

Fax: 512-249-6734

Phone: 512-533-1038

Fax: 512-249-6734

DATE PREPARED

June 10, 2003

CLASSIFICATION NAME

Prosthesis, Hip, Cement Restrictor

COMMON NAME

Cement Restrictor

PROPRIETARY NAME

Spinal Concepts Inc. Fortitude™ Cement Restrictor

DEVICE DESCRIPTION

Fortitude, cleared as a cement restrictor via K021719, is currently crafted from titanium alloy (ASTM F136). The purpose of this special 510(k) is to obtain clearance to market a PEEK OPTIMA™ (polyaryletheretherketone, ASTM F2026) version of Fortitude. The modification does not change the intended use or the fundamental scientific technology of the device.

As PEEK OPTIMA™ is radiolucent, radiographic markers are included in the distal and proximal ends of the PEEK implants. The markers consist of tantalum wires (ASTM F560) that are press-fit into small holes in the implant.

Fortitude is a hollow device with texture on two opposing flat sides, and is offered in straight and tapered styles of various sizes. Fortitude is intended for restriction of bone cement in the distal femoral canal (see figure below).

INDICATIONS:

The Fortitude Cement Restrictor System is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.

This device is not intended for any spinal indications. The safety and effectiveness of this device when implanted in the spine have not been established.

MECHANICAL TEST DATA

No mechanical tests were performed to support this application.



JUL 24 2003

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa Peterson
Regulatory Affairs Specialist
Spinal Concepts, Inc.
5301 Riata Park Court, Building F
Austin, Texas 78727

Re: K031837
Trade Name: Fortitude™ Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: June 10, 2003
Received: June 24, 2003

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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 (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's package insert and also as a Warning on the product label:

WARNING: THIS DEVICE IS NOT INTENDED FOR ANY SPINAL INDICATIONS.

**THE SAFETY AND EFFECTIVENESS OF THIS DEVICE WHEN
IMPLANTED IN THE SPINE HAVE NOT BEEN ESTABLISHED.**

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.

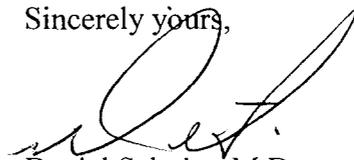
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html>

Sincerely yours,



Daniel Schultz, M.D.

Director

Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K031837

Device Name: Spinal Concepts, Inc. **Fortitude™ Cement Restrictor**

Indications for Use: The Fortitude Cement Restrictor is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.

This device is not intended for any spinal indications. The safety and effectiveness of this device when implanted in the spine have not been established.


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

510(k) Number K031837

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____
(Per 21 CFR 801.109)
1/2/96)

OR

Over-The-Counter
(Optional Format)