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K031318

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Spinal Concepts, Inc.
TraXis™ Cement Restrictor

510(k) Summary

SUBMITTED BY	Spinal Concepts, Inc. 5301 Riata Park Court, Bldg. F Austin, TX 78727
ESTABLISHMENT REGISTRATION NUMBER	1649384
CONTACT PERSON	Primary Lisa Peterson Regulatory Affairs Specialist Phone: 512-533-1080 Fax: 512-249-6734
	Alternate David M. Hooper, Ph.D. Director, Clinical and Regulatory Affairs Phone: 512-533-1038 Fax: 512-249-6734
DATE PREPARED	April 18, 2003
CLASSIFICATION NAME	Prosthesis, Hip, Cement Restrictor
COMMON NAME	Cement Restrictor
PROPRIETARY NAME	Spinal Concepts Inc. TraXis™ Cement Restrictor
PREDICATE DEVICE	Spinal Concepts Inc. Cadence™ Cement Restrictor.

DEVICE DESCRIPTION

The Spinal Concepts Inc. TraXis Cement Restrictor is a modified version of the Spinal Concepts Cadence Cement Restrictor (K022218 and K023647). Both are indicated for use as cement restrictors in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.

TraXis is crafted from titanium alloy (ASTM F136) or PEEK OPTIMA™ (polyaryletheretherketone, ASTM F2026). 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.

TraXis is offered in various lengths, widths and heights. TraXis is intended for restriction of bone cement in the distal femoral canal.

INDICATIONS:
The TraXis 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2003

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

Re: K031318
Trade/Device Name: TraXis Cement Restrictor System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: JDK
Dated: June 24, 2003
Received: June 26, 2003

Dear Ms. Peterson:

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). 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 labeling:

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.

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.

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 Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/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): K031318

Device Name:

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

Indications for Use:

The TraXis 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____ OR Over-The-Counter: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K031318