OCT 7 - 2005

510(k) Summary of Safety and Effectiveness

Safe Medical Devices Act of 1990 (SMDA)

510(k) Summary – NovaSpine Cement Restrictor

Name of Firm:	NovaSpine LLC 15 Heritage Court Tarrytown, NY 10591 Telephone: 914-909-6577 Fax: 914-909-6577
510(k) Contact:	Mr. Hamid Khosrowshahi NovaSpine LLC PO Box 969 Elmsford, NY 10523
Trade Name:	NovaSpine Cement Restrictor "NSCR"
Common Name:	Cement Restrictor
Classification:	Prosthesis, Hip Cement Restrictor CFR 878.3300 Class II
Device product Code	JDK
Substantial Equivalency	Medtronics Sofamore Danek USA, Inc.: (K003718, K011443, K012255, K013014) Spinal Concepts, Inc.: (K022218, K021719, K031837, K03118)

Device Description:

The NovaSpine Cement Restrictor "NSCR" is an implanted device for use as non-load bearing cement containment in orthopedic surgery. It will be used to contain standard bone cement such as Polymethylmethacrylate (PMMA) in the diaphysical canal of the femur or tibia.

The device is a straight or tapered rectangular hollow box construction with serrations on two opposite sides and flat surfaces on the remaining two sides. The device is fenestrated on all sides. The device is made in a variety of sizes the use of which will be determined by the responsible surgeon in accordance with the physical characteristics of each patient.

Intended use:

The NovaSpine Cement Restrictor "NSCR" is intended for use in orthopedic surgeries involving the femoral canal or the tibia.

This device is not intended for use in any spinal indications. The safety and effectiveness of this device for implantation in the spine has not been established.

Material:

The NovaSpine Cement Restrictor "NSCR" is manufactured of a 6-4 Titanium alloy as specified in ASTM F136 (latest version) or equivalent ISO 5832-3. This material specification is for material to be used in the manufacture of titanium implants.

Performance Data:

This is designated as a non-load bearing Class II device under CFR 21 878.3300 and no mechanical tests are required.

Basis For Substantial Equivalence:

This product is substantially equivalent to similar devices with similar technical specifications currently on the market such as:
Medtronics Sofamore Danek USA, Inc. (K003718, K011443, K012255, K013014) and
Spinal Concepts, Inc. (K022218, K021719, K031837, K03118).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 7 2005

Mr. Hamid Khosrowshahi
President
NovaSpine LLC
PO Box 969
Elmsford, NY 10523

Re: K051607
NovaSpine Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: JDK
Dated: August 5, 2005
Received: August 7, 2005

Dear Mr. Khosrowshahi:

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.

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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K051607

Device Name: NovaSpine Cement Restrictor

Indications For Use:

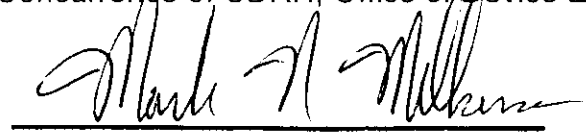
The NovaSpine Cement Restrictor device is intended for use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal and tibial plateau in hip stem and total knee replacement.

The NovaSpine Cement Restrictoris NOT intended for any spinal indications.

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 K051607