K030767
p 1 of 2

DEC 2 2 2003

510(k) SUMMARY

SUBMITTED BY

Diane Johnson
Spine Next America
4720 Salisbury Road
Suite 135
Jacksonville, FL 32256

Date Submitted: March 7, 2003

CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Prosthesis, Hip, Cement Restrictor
Common/Usual Name:	Cement Restrictor
Product Classification:	Class II
Proprietary Name:	Fidji Small Cement Restrictor

PREDICATE DEVICE

Cement Restrictor (CR) manufactured by Medtronic Sofamor Danek USA, Inc. [reference 510(k) K013663 cleared December 5, 2001]

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

DEVICE DESCRIPTION AND MATERIALS OF CONSTRUCTION

The Fidji Small Cement Restrictor is a hollow, trapezoidal block that is machined from extruded Polyetheretherketone (PEEK), which complies with ASTM F202. It contains a titanium alloy, removable anchor that is designed to aid in maintaining its position within the medullary space of the femur or humerus. It also contains tantalum inserts that serve as location and orientation markers for radiographs.

INDICATIONS FOR USE

This device is intended for use in conjunction with standard PMMA cement. The Fidji Small Cement Restrictor is designed to occlude the medullary canal before the introduction of PMMA cement during surgeries such as arthroplasty. It is also designed to prevent cement from flowing down the diaphysis thereby facilitating cement pressurization.

K030767
p 2 of 2

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.

COMPARISON TO THE PREDICATE DEVICE

In general, both the Spine Next Fidji Small Cement Restrictor and its predicate device, the Medtronic Sofamor Danek Cement Restrictor, are devices that are used as for occlusion of the medullary canal before the introduction of PMMA cement during surgeries such as total hip arthroplasty, as well as for the prevention of cement from flowing down the diaphysis thereby facilitating cement pressurization. Neither of theses devices is intended for use in spinal indications. Technologically they are virtually identical in their function and principle of operation.

Both devices are similar in that they are not intended for use under load conditions. They both serve as a cement restrictor in the medullary canal with similar surgical techniques for implantation. Both devices have similar mechanical compression characteristics since their material of construction is identical.

Conclusion: The Spine Next Fidji Small Cement Restrictor Device is substantially equivalent to the Medtronic Sofamor Danek Cement Restrictor (K013663) based upon the devices' similarities in functional design, performance, safety, and indications-for - use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2 2003

Ms. Diane Johnson
Director, Regulatory Affairs
Spine Next America Corporation
104 Greenwood Creek Road
Queenstown, Maryland 21658

Re: K030767 and K030871
FIDJI Small Cement Restrictor and FIDJI Large Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: JDK
Dated: November 3, 2003
Received: November 4, 2003

Dear Ms. Johnson:

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 G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosures (2)

510(k) Number (if known): K030767

Device Name: Spine Next® Fidji® Small Cement Restrictor

Indications for Use:

The Fidji Small Cement Restrictor is intended for use in conjunction with standard PMMA cement and is designed to occlude the medullary canal during the introduction of the cement during surgeries such as arthroplasty. It is also designed to prevent cement from flowing down the diaphysis thereby facilitating cement pressurization.

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)

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

510(k) Number K030767

Prescription Use ✓ **OR** **Over-The-Counter Use**
(PER 21 CFR 801.109)

Optional Format 1-2-96