510(k) Summary

K011943

Company: Kensey Nash Corporation
Address: 55 East Uwchlan Avenue
Exton, PA 19341 USA
Phone: 610-524-0188
Fax: 610-524-0265

Proprietary Name: ImproVise™ Absorbable Cement Flow Restrictor
Common Name: Bone Plug
Classification Name and Reference: Cement Obturator (reference unknown)
Proposed Regulatory Class: Class II
Device Product Code: LZN

For information, contact:

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Regulatory Affairs Manager
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Date Summary Prepared: June 20, 2001*

Device Description:

The ImproVise™ Absorbable Cement Flow Restrictor is designed to provide a quick, simple, and effective method of plugging the intramedullary canal with an easy-to-place absorbable foam plug. Based on the size of the reamer used to form the channel, the appropriate size cement restrictor is selected and is then guided into the canal to the desired depth, using the ImproVise™ insertion tool. Plugs will be preloaded onto the tip of the tool. The ImproVise™ foam plugs are deformable and can take on the irregular shape of the canal, effectively sealing the canal at the friction-fit point. The cement restrictors are available in sizes small, medium, large and extra-large (respectively, diameters of 9.5-11 mm, 11-13 mm, 13-15 mm, and 15-17.5 mm), both in straight cylindrical and tapered versions. The restrictor can be easily carved with a scalpel at the time of surgery or press-fit into the bone. The ImproVise™ Absorbable Cement Flow Restrictor is manufactured from a proprietary polylactic acid foam. A proprietary foaming process creates a structure which is greater than 90% void space.

Intended Use:

The ImproVise™ Absorbable Cement Flow Restrictor is intended for use as an absorbable bone cement flow restrictor plug for use in the intramedullary canal. This device is not intended for use in the spine.

Substantial Equivalence:

The intended use, material and design of the ImproVise™ Absorbable Cement Flow Restrictor are nearly identical and thus substantially equivalent to the Resorbaplug™ Bone Plug cleared by 510(k) for Danek Group (now the Sofamor Danek division of Medtronic, Inc.) (K920118). See Table 1 below for a comparison of the two devices.

*Revised December 12, 2001.

Table 1: Substantial Equivalence of ImproVise™ and Resorbaplug™

	ImproVise™ Absorbable Cement Flow Restrictor (Kensey Nash Corporation)	**Resorbaplug™ Bone Plug (Danek Group)**
Status	New Device	Predicate
Intended Use	Bone cement flow restrictor for intra-medullary canal	Bone cement flow restrictor for intramedullary canal
Target Population	Patients undergoing orthopedic procedures (large joint replacement requiring use of bone cement)	Patients undergoing orthopedic procedures (large joint replacement requiring use of bone cement)
Anatomical Sites of Use	Orthopedic procedures in the long bones	Orthopedic procedures in the long bones
Material	Polylactic acid	Polylactic acid
Architecture	Foam	Foam
Manufacturing Process	Proprietary foaming process	Proprietary foaming process
Shape	Cone, cylinder	Cone, cylinder
Size	Small (9.5-11 mm), medium (11-13 mm), large (13-15 mm), and extra-large (15-17.5 mm)	14, 20 and 26 mm in diameter
Sterilization	Gamma radiation	Gamma radiation
Where Used	Hospital operating room	Hospital operating room
Principle of Operation	Foam plug conforms to shape of intramedullary canal and is friction fit to proper depth; plug prevents bone cement from migrating deeper into the canal.	Foam plug conforms to shape of intramedullary canal and is friction fit to proper depth; plug prevents bone cement from migrating deeper into the canal.
Performance Interference fit that provides 100N push-out force	1.9-2.9 mm	2.5 mm
Safety Characteristics	Biocompatibility of material, demonstrated push-out forces	Biocompatibility of material, demonstrated push-out forces

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Ms. Julie N. Broderick
Vice President of Clinical
and Regulatory Affairs
Kensey Nash Corporation
55 East Uwchlan Avenue
Exton, Pennsylvania 19341

Re: K011943
Trade/Device Name: Impro Vise™ Absorbable Cement Flow Restrictor
Regulation Number: 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: LZN
Dated: June 20, 2001
Received: June 21, 2001

Dear Ms. Broderick:

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 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,

Celia M. Witten, Ph.D., M.D.
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): K011943

DEVICE NAME: ImproVise™ Absorbable Cement Flow Restrictor

INDICATIONS FOR USE:

The ImproVise™ Absorbable Cement Flow Restrictor is intended for use as an absorbable bone cement flow restrictor plug for use in the intramedullary canal. This device is not intended for use in the spine.

Please do not write below this line – Use another page if needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-counter Use _____
(per 21 CFR 801.109)

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

510(k) Number K011943