K060917

Kensey Nash

510(k) Summary

SEP 22 2006

Submitted by: Kensey Nash Corporation
735 Pennsylvania Drive
Exton, PA 19341

Contact Person: Jennifer J. Bosley, MBA, RAC
Regulatory Affairs Specialist
Ph: (484) 713-2173 Fax: (484) 713-2903

Date Prepared: September 14, 2006
510(k) #: **K060917**
Device Trade Name: Kensey Nash Bone Void Filler
Common/Usual Name: Bone Void Filler
Proposed Classification: Resorbable Calcium Salt Bone Void Filler Device
21CFR§888.3045
Class II, MQV—87Orthopedics

Device Description:
Kensey Nash Bone Void Filler is a mixture of beta tricalcium phosphate, polylactic acid and Type I bovine collagen. The product will be provided gamma sterilized for one-time use in a variety of shapes ranging from pre-formed cylinders, granules, cubes and blocks with sizes ranging up to 25 mm in diameter and up to 30 cc in volume.

Intended Use:
The Kensey Nash Bone Void Filler is intended to be gently packed into the bony voids or gaps of the extremities and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure. These defects may be created from traumatic injury to the bone or surgically created osseous defects for the harvest of bone. The device provides a bone void filler that resorbs and is replaced with bone during the healing process. The device may be combined with sterile fluids such as saline or autogenous blood products such as blood or bone marrow aspirate. The addition of these autogenous blood products does not alter the performance of the device.

Predicate Devices:

MANUFACTURER	DEVICE	510(k) #
OsteoBiologics	PolyGraft™ BGS	K040047
OsteoBiologics	PolyGraft™ TCP	K033707
Kensey Nash [Centerpulse Spine-Tech]	CopiOs™ Bone Void Filler	K033679
Medtronic	MasterGraft® Putty	K051386

Substantial Equivalence:
Kensey Nash BVF is substantially equivalent to the legally marketed predicate devices with regard to intended use, materials, physical structure, principle of operation and technological characteristics. Results of *in vivo* and *in vitro* comparison testing demonstrate that Kensey Nash BVF is substantially equivalent to PolyGraft™ BGS.

Non-Clinical Testing:
Kensey Nash BVF has undergone non-clinical testing that provides reasonable assurance of safety and effectiveness for its intended use. Testing included biocompatibility, physical properties testing, compressive strength and an animal study.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 22 2006

Kensey Nash Corporation
% Ms. Jennifer J. Bosley
Regulatory Affairs Specialist
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K060917
Trade/Device Name: Kensey Nash Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: August 21, 2006
Received: August 22, 2006

Dear Ms. Bosley:

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), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

510(k) Number: K060917

Device Name: Kensey Nash Bone Void Filler

Indications For Use:

The Kensey Nash Bone Void Filler is intended to be gently packed into the bony voids or gaps of the extremities and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure. These defects may be created from traumatic injury to the bone or surgically created osseous defects for the harvest of bone. The device provides a bone void filler that resorbs and is replaced with bone during the healing process. The device may be combined with sterile fluids such as saline or autogenous blood products such as blood or bone marrow aspirate. The addition of these autogenous products does not alter the performance of the device.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

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

510(k) Number K060917