NOV 22 2011

510(k) Summary

Pioneer Surgical Technology
NB3D Bone Void Filler

November 21, 2011

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Pioneer Surgical Technology 375 River Park Circle Marquette, MI 49855 Telephone: +1 (906) 226-4812 Fax: +1 (906) 226-4459
Official Contact:	Jonathan Gilbert

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	NB3D Bone Void Filler
Common Name:	Bone Void Filler
Classification Regulations:	Filler, Bone Void, Calcium Compound 21 CFR 888.3045 Class II
Product Code:	MQV
Classification Panel:	Orthopaedic and Rehabilitation Devices Panel
Reviewing Branch:	Restorative Devices Branch

INTENDED USE

NB3D Bone Void Filler is intended for bony voids or gaps that are not intrinsic to the stability of bony structure. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product is intended to be used in conjunction with bone marrow aspirate and autograft bone as a bone graft extender and gently packed into bony voids or gaps in the posterolateral spine. NB3D provides an open void/gap filler that resorbs and is replaced by the growth of new bone during the healing process.

DEVICE DESCRIPTION

NB3D is a resorbable porous, calcium phosphate bone void filler that provides a scaffold for the in-growth of new bone. NB3D is an osteoconductive implant with an interconnected porosity similar to human cancellous bone.

EQUIVALENCE TO MARKETED DEVICES

Pioneer Surgical Technology submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, NB3D Bone Void Filler (NB3D) is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices:

Pioneer Surgical Technology FortrOss Bone Void Filler cleared under K091031;

Orthovita, Inc. Vitoss® Bioactive Foam Bone Graft Substitute-STRIP and PACK, cleared under K081439;

Synthes (USA) chronOS™ Composite, cleared under K071046; and

Medtronic Sofamor Danek MASTERGRAFT® Strip, cleared under K082166.

The subject device and the predicate devices are bone void fillers that are intended for bony voids or gaps that are not intrinsic to the stability of the bony structure.

Characterization testing performed included methods described in ISO 10993-3, ISO 10993-5, ISO 10993-10, ISO 10993-11, and ASTM F1185. Animal testing performed to demonstrate substantial equivalence included determination of radiographic, biomechanical, histological and other characteristics of the subject device and the predicate Vitoss Bioactive device in a rabbit posterolateral spine fusion model.

Overall, NB3D has the following similarities to the remaining predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 22 2011

Pioneer Surgical Technology, Inc.
% PaxMed International, LLC
Mr. Floyd G. Larson
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K111944
Trade/Device Name: NB3D Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bond void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: November 10, 2011
Received: November 14, 2011

Dear Mr. Larson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number: K111944

Device Name: NB3D Bone Void Filler:

Indications for Use:

NB3D Bone Void Filler is intended for bony voids or gaps that are not intrinsic to the stability of bony structure. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product is intended to be used in conjunction with bone marrow aspirate and autograft bone as a bone graft extender and gently packed into bony voids or gaps in the posterolateral spine. NB3D provides an open void/gap filler that resorbs and is replaced by the growth of new bone during the healing process.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111944