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XI. 510(k) Summary

SUBMITTER: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02780
Tel: 508-828-3537
Fax: 508-828-3711

OCT 13 2006

CONTACT PERSON: Melanie Archer

DATE PREPARED: August 23, 2006

CLASSIFICATION NAME: Resorbable calcium salt bone void filler
Piston Syringe

PROPRIETARY NAME: HEALOS® FX Bone Graft Substitute
HEALOS® FX Graft Mixing and Delivery System

PREDICATE DEVICES: HEALOS® Bone Graft Substitute (K012751 and K043308)
Vitoss® Scaffold Foam Bone Graft Material (K032288)
Symphony® Graft Delivery System (K003286)
Harvest® Graft Delivery System (K043261)
Imbibe® II Syringe (K030208)

DEVICE DESCRIPTION:

HEALOS® FX Bone Graft Substitute:
HEALOS® FX Bone Graft Substitute ("HEALOS® FX"), combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. The principal components of the HEALOS® FX Bone Graft Substitute are Type I bovine collagen and hydroxyapatite that are resorbed and remodeled into new bone as part of the natural healing process.

HEALOS® FX Graft Mixing and Delivery System:
The HEALOS® FX Graft Mixing and Delivery System is indicated for the mixing and delivery of HEALOS® FX to a surgical site.

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INTENDED USE:

HEALOS® FX Bone Graft Substitute:

HEALOS® FX Bone Graft Substitute ("HEALOS FX"), combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. HEALOS®FX is a bone graft substitute that is resorbed and remodeled into new bone as part of the natural healing process.

HEALOS® FX Graft Mixing and Delivery System Indications for Use:
The HEALOS® FX Graft Mixing and Delivery System is indicated for the mixing and delivery of HEALOS® FX to a surgical site.

MATERIALS:

HEALOS® FX Bone Graft Substitute:
Calcium salt with Type I bovine collagen.

HEALOS® FX Graft Mixing and Delivery System:
Makrolon Rx2530-1118, Cycolac ABS MG47MD, EPDM, Loctite cyanoacrylate, polyethylene, acrylic copolymer.

PERFORMANCE DATA:

HEALOS® FX Bone Graft Substitute:
A performance evaluation has been included to support the safety and effectiveness of HEALOS®FX compared to the predicate devices.

HEALOS® FX Graft Mixing and Delivery System:
No performance standards have been established for this type of device. The substantial equivalence of the HEALOS® FX Graft Mixing and Delivery System to the predicate devices (Symphony Graft Delivery System (K003286), Harvest Graft Delivery System (K043261), and Imbibe II Syringe (K030208) is based upon equivalence in design, principles of operation, indications and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 13 2006

DePuy Spine, Inc
% Ms. Melanie Archer
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K062495
Trade/Device Name: HEALOS® FX Bone Graft Substitute, HEALOS® Graft Mixing and Deliver Systems
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, FMF
Dated: August 23, 2006
Received: August 25, 2006

Dear Ms. Archer:

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, and 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,

For

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

IV. Indications for Use

510(k) Number (if known): K062495

Device Name: HEALOS® FX Bone Graft Substitute
HEALOS® FX Graft Mixing and Delivery System

HEALOS® FX Bone Graft Substitute Indications For Use:

HEALOS® FX Bone Graft Substitute ("HEALOS FX"), combined with autogenous bone marrow, is intended for use in filling bony voids or gaps of the skeletal system (i.e., the extremities, spine, and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. HEALOS® FX is a bone graft substitute that is resorbed and remodeled into new bone as part of the natural healing process.

HEALOS® FX Graft Mixing and Delivery System Indications for Use:

The HEALOS® FX Graft Mixing and Delivery System is indicated for the mixing and delivery of HEALOS® FX to a surgical site.

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 K062495