

MAY 25 2010

**510(k) Summary**

**Submitter:** DePuy Spine, Inc.  
325 Paramount Drive  
Raynham, MA 02767

**Contact Person:** Sharon Starowicz  
Director of Regulatory Affairs  
Voice: (508) 828-2867  
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**Date Prepared:** April 27, 2010

**Device Class:** Class II

**Classification Name:** Bone grafting material  
§872.3930

Classification Panel: Dental

FDA Panel Number: 76

**Product Code(s):** LYC and NPM

**Proprietary Name:** HEALOS Dental Bone Graft Substitute

**Predicate Devices:** HEALOS Dental Bone Graft Substitute (K081432)

**Device Description:** HEALOS Dental Bone Graft Substitute is a mineralized collagen matrix processed into lyophilized strips or pads for surgical implantation. The principal components of the HEALOS Dental Bone Graft Substitute are Type I bovine collagen and hydroxyapatite. HEALOS Dental Bone Graft Substitute is approximately 30% mineral by weight. The subject of this 510(k) is to add additional size configurations. The formulation is identical to the predicate device- HEALOS Dental Bone Graft Substitute. There are no changes to the material, chemical composition, physical structure, or indications for use of the product.

**Intended Use:** HEALOS Dental Bone Graft Substitute is intended to fill, augment, or reconstruct periodontal and/or bony defects of the upper or lower jaw. HEALOS is a bone graft substitute that is resorbed and remodeled into new bone as part of the natural healing process.

**Materials:** The principal components of HEALOS Dental Bone Graft Substitute are Type I bovine collagen and hydroxyapatite.

**Performance Data:** No performance standards have been established for this type of device. Preclinical testing has been completed to verify the subject device has the same characteristics as the predicate device.

**Conclusion:** Based on the predicate comparison and testing, the subject device HEALOS Dental Bone Graft Substitute is substantially equivalent to the predicate device.



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

Ms. Sharon Starowicz  
Director of Regulatory Affairs  
DePuy Spine, Incorporated  
325 Paramount Drive  
Raynham, Massachusetts 02767

MAY 25 2010

Re: K093390  
Trade/Device Name: HEALOS Dental Bone Graft Substitute  
Regulation Number: 21 CFR 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: II  
Product Code: LYC, NPM  
Dated: April 27, 2010  
Received: April 28, 2010

Dear Ms. Starowicz:

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.

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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

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: HEALOS Dental Bone Graft Substitute

Indications For Use:

HEALOS Dental Bone Graft Material ("HEALOS"), is intended to fill, augment, or reconstruct periodontal and/or bony defects of the upper or lower jaw. HEALOS is a bone graft substitute that is resorbed and remodeled into new bone as part of the natural healing process.

Ken Maly for MSR  
(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K093390

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use       
(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)