MAY 13 2011

K110449

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.92

Submitter:	BIOMET *3i*
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Establishment Registration Number:	1038806
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Date Prepared:	02/14/2011
Trade/Proprietary Name:	Endobon Xenograft Granules
Address of Sponsor:	BIOMET 3i 4555 Riverside Drive Palm Beach Gardens, FL 33410
Common/Usual Name:	Xenograft Hydroxyapatite Bovine Derived Granules
Classification Name:	Class II 21 CFR §872.3930 / LYC
Device Classification:	The Office of Device Evaluation Center for Devices and Radiological Health – Dental Devices Branch Food and Drug Administration, has classified Bone Grafting Material as Class II

	device pursuant to 21 C.F.R. § 872.3930 regulations.
Legally Marketed Predicate Devices:	**Name of Manufacturer:** GEISTLICH PHARMA AG CH - 6110 Wolhusen Switzerland Washington, DC 20036 **Device Name:** Xenograft Bone Granules (Bovine) **Device Trade Name:** BioOss
Purpose of the Traditional 510(k) notice:	Endobon Xenograft Granules is a modification to Endobon Xenograft Granules, K980679. The purpose of this 510K is to add Sinus Elevation to the current Indication for Use.
Device Description:	Endobon Xenograft Granules consist of bovine derived hydroxyapatite ceramic granules.
Intended Use:	Endobon Xenograft Granules are used in the following dental and/or surgical procedures: • Alveolar ridge augmentation/reconstruction, • Sinus elevation, • Filling of resection defects in benign bone tumor, bone cysts, or other defects in the alveolar ridge or wall, • Filling of bone defects after apicectomy, • Filling alveoli after tooth extraction. This product should not be used in non-peridontal mandibular applications.
Technological Characteristics:	Endobon - hydroxyapatite xenograft granules are derived from cancellous bovine bone that are used as an implantable material to function as a non-resorbable osteoconductive scaffold for dental applications. A two-step, high-temperature manufacturing process (pyrolysis at a temperature above 900 °C and sintering at a temperature above 1200°C) allows complete deproteinization as well as destruction of potential residual bacteria, virus and prions. The slow resorption rate attributed to Endobon and other similar materials processed in the same manner relates to the crystalline-like structure of 95% of the hydroxyapatite (HA) in Endobon. The resorption rate of hydroxyapatite (HA) increases as crystallinity decreases, and the crystallinity is highly dependent on the sintering temperature. High sintering temperature lowers the degradation of the biomaterial due to an

increase in crystallinity.

The precise chemical name of the hydroxyapatite is pentacalcium hydroxide (tris) phosphate [$Ca_5(PO4)_3OH$]. Semiquantitative Energy-Dispersive Spectrometry (EDS) analysis of the chemical composition of both Endobon and Bio-Oss grafting materials from Jensen et al. 1996 are presented in Table 1. The data demonstrates similarities in both weight percentage and atomic percentage of the elements.

	Ca		P		Na		Si		Mg		Cl	
	Wt %	*At %*	*Wt %*	*At %*	*Wt %*	*At %*	*Wt %*	*At %*	*Wt %*	*At %*	*Wt %*	*At %*
Endobon	68.2	61.3	26.4	30.6	1.6	2.5	0.6	0.7	3.3	4.9	0	0
Bio-Oss	64.4	59.3	27.2	31.4	2.9	4.5	1.6	2.0	1.6	2.4	0.4	0.4

Table 1

Nonclinical Performance Data: N/A

Clinical Data: N/A

Performance Standards: Though there is a Guidance Document for this type of product: "Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices" it was not utilized as part of this submission.

Substantial Equivalence Endobon Xenograft Granules has the same intended use and, physiochemical properties as BioOss. Any differences in material, chemical composition, or physical structure, do not raise any new questions of safety or effectiveness. Extensive equivalency assessments demonstrates that Endobon Xenograft Granules is as safe and effective as BioOss. Thus; the Endobon Xenograft Granules is substantially equivalent to its predicate device.

Conclusion: Base on the predicate comparison, literature review and equivalency assessment, Endobon Xenograft Granules 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. Martha I. Garay
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Biomet 3I
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

MAY 13 2011

Re: K110449
Trade/Device Name: Endobon Xenograft Granules
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: May 6, 2011
Received: May 9, 2011

Dear Ms. Garay:

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

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

K110449

Indications for Use

510(k) Number (if known): **K110449**

Device Name: **Endobon Xenograft Granules**

Indications for Use:

Endobon® Xenograft Granules are used in the following dental and/or surgical procedures:

- Alveolar ridge augmentation/reconstruction.
- Filling of defects after root resection, apicoectomy, and cystectomy.
- Filling alveoli after tooth extraction.
- Sinus elevation.

This product should not be used in non-peridontal mandibular applications.

Prescription Use **X**		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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