K091424

1074

510(k) Summary

As Required by 21 section 807.92 (c)

AUG 18 2010

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5-Contact Person: Mr Dimitri Markoulides (Managing director)
6-Date summary prepared: 29 July, 2010
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11- Contact Person: Jay Mansour, President

12-Device Trade or Proprietary Name: Osta Maxigro™ and **Osta Regigro™**

13-Device Common or usual name: Anorganic Bovine Bone grafting material

14-Device Classification Name: Bone Filling Material

15-Substantial Equivalency is claimed against Bio Oss, cleared under K033815

16-Description of the Device:

Osta Maxigro™ and Osta Regigro™ are natural bone minerals which have been derived from a bovine extract. The material is essentially free from collagen and comprises of a highly purified mineral structure with micropores and trabecules which is comparable to that of human bone. The materials are prepared by extracting the fat and removal of the collagen, thereby resulting in a pure bone mineral that is sintered in block form and then crushed to form powder granules. This natural sponge like geometry comprising of Hydroxyapatite nano-crystalls results in a high internal surface area scaffold that typically exceeds $100m^2/g$ for Osta Maxigro™ and $80m^2/g$ for Osta Regigro™. The high surface area properties of these materials make them ideal for allowing blood flow to the wound site where bony contact is established during the bone remodeling process. Osta Maxigro™ and Osta Regigro™ have low crystallinities comparable to that of human bone which is completely resorbed and replaced by host bone during bone regeneration process. The materials support bone formation but do not induce bone formation. Osta Maxigro™ and Osta Regigro™ are available in powder or block form and both undergo final sterilization by γ- radiation. A combination of Osta Maxigro™ blocks and granules can be utilized for the indications shown below depending on the defect size. Osta Maxigro™ Blocks is ideally recommended for filling of large bone cavities with limited bone height and or wall thickness.

17-Intended Use:

Osta Maxigro™ in both forms (powder & blocks) and Osta Regigro™ in both forms (powder & blocks) are Recommended for:

- Filling of large oral and maxillofacial intra-osseous cavities

18-Indications for Use: (refer to FDA form attached)

1. Augmentation or reconstructive treatment of alveolar ridge
2. Filling of periodontal defects
3. Filling of defects after root resection, apicectomy, and cystectomy
4. Filling of extraction sockets to enhance preservation of the alveolar ridge
5. Elevation of maxillary sinus floor
6. Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)

19-Technological Characteristics

TECHNOLOGICAL CHARACTERISTICS	Comparison between K091424 and K033815	Location of justification within K091424 submission
Indications for use	Identical-See above	510k Summary
Target population	Identical- Not for patients who exhibit Hyperthyroidism, Osteoporosis, Osteomalacia, Liver disease and renal dysfunction, diabetes and acute or chronic infections.	Device Labeling
Design	Similar, the only slight difference being is that Osta Maxigro has higher surface area than the predicate due to a higher volume of micropores which is closer to mimicking that of natural bone. The higher surface area of the device is not detrimental to the performance characteristics of the device relative to the predicate as verified by dissolution and implantation tests. Osta Regigro has an identical surface area to the predicate and has the same volume of micropores.	Original Submission Tab15 pp4-11
Materials	Similar, both devices are sourced from bovine femurs and are treated with similar thermal treatments.	S2-Tab 3
Performance	Similar, there is no statistical difference between the dissolution characteristics or immunogenic responses from implantation testing.	S2-Tab G Original Submission Tab F
Sterility	Similar both conform to ISO11137 in using a sterilization cycle validated sterility assurance level (SAL) of $1x10^{-6}$	Original Submission Tab P
Biocompatibility	Similar both conform to the requirements of the bluebook memorandum G95-1 which encompasses the following: Cytotoxicity testing ISO 10993-5 Intracutaneous Injection ISO 10993-5 Sensitization testing ISO 10993-10 Genotoxicity Testing ISO 10993-3 Implantation Testing ISO 10933-6	Original Submission Tab 18 Original Submission Tab 18 Original Submission Tab 18 S2 Tab A Original Submission Tab B-F

Mechanical safety	Similar in Compressive Strength and Young's Modulus, however Osta Maxigro & Osta Regigro Are not intended for loading.	Original Submission Tab 15
Chemical composition	Similar, based on Chemical Analysis, XRD, FTIR and Crystallinity analysis. The similar dissolution performance characteristics are evidence that the chemical composition is very similar.	Original Submission Tab 15
Chemical safety	Not applicable	
Anatomical sites	Identical- Periodontal and Maxillo Facial	
Human factors	Not applicable	
Energy used and/or delivered	Not Applicable	
Compatibility with environment and other devices	Not Applicable.	
Where used	Identical, both devices have the same intended uses except for implant loading	510k Summary
Standards met	Similar, they comply with Cytotoxicity testing ISO 10993-5 Intracutaneous Injection ISO 10993-10 Sensitization testing ISO 10993-10 Genotoxicity Testing ISO 10993-3 Implantation Testing ISO 10933-6	
Electrical safety	Not applicable	
Thermal safety	Not applicable	
Radiation safety	Not applicable	

19- Brief discussion of the non clinical tests submitted, referenced or relied on in this 510k submission.

Effectiveness discussion

Assessment of the performance characteristics of the Osta Maxigro™ and Osta Regigro™ was carried out by a full chemical and physical characterization of the test devices relative to the predicate. The physical and chemical characteristics of the devices were comparable to the predicate; however, the key performance output that has a direct link to the chemical and physical characteristics was the dissolution performance of the devices relative to the predicate. It is well accepted that the in vitro dissolution rate comparisons of the devices relative to the predicate would be indicative of the in vivo resorption rates which would demonstrate substantially equivalence to the predicate. Given that at 99% confidence there was no significant difference in the dissolution rates of the devices (in either form powder or block) to the predicate, it follows that from a performance characteristic point of view, the devices would be as effective as that of the predicate.

Safety discussion

From a biological tolerance point of view the Osta Maxigro™ and Osta Regigro™ devices were tested individually regarding cytotixicity according to ISO 10993-5 and intracutaneous injection (ISO 10993-5) and in combination testing for cytotoxicity, sensitization testing ISO10993-10 and genotoxic screening (ISO 10993-3). It should be borne in mind that both Osta Maxigro™ and Osta Regigro™ devices are exposed to the same chemical treatments for the same times during processing. The Osta Maxigro™ and Osta Regigro™ devices conformed to all the standards mentioned above regarding safety. An in vivo implantation muscle pouch study also concluded that at 99% confidence there was no significant difference, regarding inflammation, encapsulation and angiogenesis with respect to the predicate as per ISO10993-6. From a sterility point of view the devices also conformed to ISO 11137 in terms of achieving a sterility level SAL $1x10^{-6}$. In terms of mitigating the potential

presence of prions, a hydrogen peroxide gas treatment was incorporated in to the process to reduce the potential presence of prions on the devices as per published data. Based on the biological screening, sterility tests and prion reduction initiatives as described above, the fact that the Osta Maxigro™ and Osta Regigro™ devices complies to all safety standards for biological tolerance means that that the devices are as safe as that of the predicate.

20-Safety and Effectiveness of the devices:

Based on the summaries in (18 &19) above it is demonstrated that Osta Maxigro™ and Osta Regigro™ devices are substantially equivalent to the predicate Bio Oss™ and are safe and effective regarding the indications for use.

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

Osta Technologies
C/O Mr. Jay Mansour
Mansour Consulting, LLC
845 Aronson Lake Court
Roswell, Georgia 30075

AUG 18 2010

Re: K091424
Trade/Device Name: Osta Maxigro ™ and Osta Regigro ™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: July 30, 2010
Received: August, 02, 2010

Dear Mr. Mansour:

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

K091424

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Indications for Use

510(k) Number (if known): K091424

Device Name: Osta Maxigro™ and Osta Regigro™

Indications For Use:

1. Augmentation or reconstructive treatment of alveolar ridge
2. Filling of periodontal defects
3. Filling of defects after root resection,apicocectomy, and cystectomy
4. Filling of extraction sockets to enhance preservation of the alveolar ridge
5. Elevation of maxillary sinus floor
6. Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR)

Prescription Use ✓ 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)

Rei Mehy for MSR

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

510(k) Number: K091424