

K102015

GENOSS

510(k) Summary

07/08/2010

NOV 19 2010

1. Company

Submitter	
Name	Genoss Co., Ltd.
Address	1F Gyeonggi R&DB Center, 906-5 Iui-dong, Suwon-si, Yeongtong-gu, Gyeonggi-do, 433-270, Korea
Phone/Fax	+82-31-888-5100/ +82-31-888-5105
Contact person	Dahye Kim / QA dhkim2@implantium.com

2. Device Name

Proprietary name: OSTEON, OSTEON Sinus, OSTEON Lifting

Common name: Bone grafting material

Classification name: Bone grafting material, Synthetic

3. Predicated Device

K062834 OSTEON

4. Description

This product is a synthetic osteoconductive bone graft substitute composed of hydroxyapatite (HA) and beta-tricalcium phosphate (β -TCP). This product presents an interconnected porous structure, similar to that of human cancellous bone. This product is available as irregular shaped particles of size 0.3~2.0 mm. It is supplied sterile by gamma irradiation.

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5. Indication for use

OSTEON, OSTEON Sinus, OSTEON Lifting are intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects.

- Periodontal/Infrabony defects
- Ridge augmentation
- Extraction sites (implant preparation/placement)
- Sinus lifts
- Cystic cavities

6. Review

OSTEON, OSTEON Sinus, OSTEON Lifting have the similar technological characteristics as the predicate device; main material, indication for use and design.

OSTEON, OSTEON Sinus, OSTEON Lifting have been subjected to extensive safety, performance and product validations prior to release. Safety tests including shelf-life, sterilization validation have been performed to ensure the devices comply with applicable international and US regulations.

7. Conclusion

Based on the information provided in this premarket notification of Genoss Co., Ltd. concludes that the five years shelf-life of OSTEON, OSTEON Sinus, OSTEON Lifting are acceptable and safe, substantially equivalent to predicate devices



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

Genocc Company, Limited
C/O Dr. Eunkyung Son
Dentium USA
11075 Knott Avenue, Suite A
Cypress, California 90630

NOV 19 2010

Re: K102015

Trade/Device Name: OSTEON, OSTEON Sinus, OSTEON Lifting

Regulation Number: 21 CFR 872.3930

Regulation Name: Bone Grafting Material

Regulatory Class: II

Product Code: LYC

Dated: October 21, 2010

Received: October 21, 2010

Dear Dr. Son:

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/ucml15809.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,



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

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Indication for use

510(k) Number:

~~K062834~~ K102015

Device Name:

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- Sinus lifts
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Prescription Use

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102015

Statement of Indication for use

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