K062834

510(k) Summary

APR 24 2007

Date: 13 September 2006

1. Company making the submission:

	Submitter
Name	GENOSS Co., Ltd.
Address	27-5Iui-dong Yeongtong-gu Suwon-si Gyeonggi-do, Republic of Korea 443-270
Phone	+82-31 207-2200
Fax	+82-31 207-3315
Contact	Keith Jung / manager
Internet	ikjung@implantium.com

2. Device :
   Proprietary Name – OSTEON
   Common Name – Bone Grafting Material
   Classification Name – Bone Grafting Material, Synthetic

3. Predicate Device : MBCP™, Biomatlante, K051885

4. Description :
   OSTEON is a synthetic resorbable osteoconductive bone graft substitute composed of Hydroxyapatite(HA) and beta-Tricalcium Phosphate (β -TCP). OSTEON presents a interconnected porosity structure, similar to that of human cancellous bone. OSTEON is available as irregular shaped powders of size 0.3~2.0 mm. It is supplied sterile.

5. Indication for use :
   OSTEON is 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 Implant System has the similar technological characteristics as the predicate device; main material, Indication for use and design.

   OSTEON has been subjected to extensive safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Conclusions :
   Based on the information provided in this premarket notification GENOSS Co., Ltd. concludes that OSTEON is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Genoss Company, Limited
C/O Mr. Klass Besseling
Consultant
Spherelink, LLC
28711 Jaeger Drive
Laguna Niguel, California 92677

APR 24 2007

Re: K062834
Trade/Device Name: OSTEON
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: April 5, 2007
Received: April 16, 2007

Dear Mr. Besseling:

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.

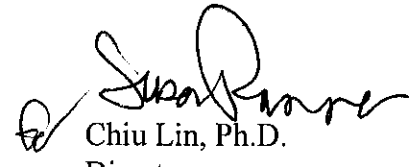
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known) K062834

Device Name: OSTEON

OSTEON is 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

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(21CFR801 Subpart D) (21CFR801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(510(k) Number K062834