DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 14, 2016

Genoss Co., Ltd.
Eunsang Lee
Manager
1F Gyeonggi R&DB Center, 105 Gwanggyo-ro,
Yeongtong-gu
Suwon-si, Gyeonggi-do, 433-270 KR

Re: K153676
Trade/Device Name: OSTEON III
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: LYC
Dated: August 8, 2016
Received: August 15, 2016

Dear Eunsang Lee:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, PhD
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153676

Device Name

OSTEON III

Indications for Use *(Describe)*

OSTEON III 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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K153676
510(k) Summary

1. Company

	Submitter
Name	GENOSS Co., Ltd.
Address	1F Gyeonggi R&DB center, 105 Gwanggyo-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 433-270, Korea
Phone/Fax	+82-31-888-5100/ +82-31-888-5595
Contact person	Eunsang Lee / RA eslee@genoss.com
Summary Date	14th September, 2016

2. Device Name

Proprietary name: OSTEON III

Common name: Bone grafting material

Classification name: Bone grafting material, Synthetic

Product Code: LYC

Regulation: 21 CFR 872.3930

3. Predicated Device

K051885 MBCP (Primary)

K040646 Straumann Granules (Reference)

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 human cancellous bone. This product is available as irregular shape particle of size 0.2~2.0mm. It is sterilized by gamma-radiation.

5. Indication for use

OSTEON III 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. Technological Characteristics

OSTEON III has the similar technological characteristics as the predicated device; main material, intended use, device design, composition of Materials, physical properties is as following.

Device name	**OSTEON III**	**MBCP**	**Straumann Granules**
Manufacturer	GENOSS	Biomatlante	Straumann
510(k) Number	New Device	K051885	K040646
Intended Use			
Indication for Use	-Periodontal/ Infrabony defects - Ridge augmentation -Extraction sites (implant preparation / placement) - Sinus lifts	- Osteogenic scaffold for bone healing - Promotes osteoblastic proliferation and differenciation. - Stimulates the osteoblastic response.	- Sinus lift - Bony defects of the alveolar ridge - Intraosseous defects - Peri-implant defects - Extraction sockets
Applicable	Human Oral, periodontal		
Function	Osteoconductive		
Device Design			
Physical morphology	Interconnecting macro and micro pores		
Performance	Bone formation		
Surgical site	Oral, Periodontal		
Package	Glass vial, Glass syringe	Glass, Plastic vial Glass syringe	Glass, Plastic vial

Composition of Materials			
Composition	Biphasic Calcium Phosphate (HA 60%+ β-TCP 40%)		
Physical Properties			
Bone material	Synthetic bone		
Phase	Biphasic (HA+ β-TCP)		
Porosity	~80%	~70%	~90%
Pore size	200~400 μm	300~600 μm	100~500 μm
Particle of Size	0.2~2.0mm	0.5~2.0mm	0.4~1.0mm
Ca/P	1.59	1.6	1.61
Crystalline phase composition	HA 60%:	HA 60%:	HA 60%:
Crystallinity	> 70%	> 70%	> 70%
Elution-pH	pH difference ≤ 1.5	pH difference ≤ 1.5	pH difference ≤ 1.5
Others			
Biocompatible	Biocompatible		
Sterilization	Gamma Irradiation		
Shelf life	1.5 years		

7. Performance Data

Biocompatibility testing on the proposed OSTEON III has been completed. Requirements for biological evaluation of the proposed device were based on the Blue Book memorandum G95-1 issued on May 1, 1995, Use of International Standard ISO10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing." The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological bone and tissues with its intended use. The following biocompatibility tests were completed:

-ISO Cytotoxicity
-ISO Pyrogencity
-ISO Systemic toxicity
-ISO Genotoxicity-Ames
-ISO Implantation
-ISO Endotoxin (LAL)
-ISO Sensitization
-ISO Intracutaneous reactivity
-ISO Subchronic toxicity
-ISO Genotoxicity-Micro nucleus
-ISO Genotoxicity-Chromosomal aberration

The proposed OSTEON III was evaluated using the following performance bench testing to confirm the performance characteristics:

- Visual Test
- Capacity
- Trace Elements
- Crystalline phase Composition
- Morphology & Surface Characteristics
- Elution Test (pH, Pb)
- Ultraviolet rays absorption spectrum
- Particle size distribution
- Shear and Elastic modulus
- Size
- Density
- Ca/P ratio
- Crystallinity
- Water Solubility
- Potassium permanganate consumed
- Resorption
- Compressive strength

All test results demonstrate that the materials chosen, the manufacturing process, and the design utilized for the OSTEON III met the established specifications necessary for consistent performance according to its intended use.

8. Substantial Equivalence

While the Indications for Use statements for the proposed and predicate devices differ, their meaning is equivalent as they share the same intended use, namely to serve as a bone grafting material to fill, augment or reconstruct various types of periodontal or oral/maxillofacial defects. The primary difference between OSTEON III and its primary predicate device MBCP (K051885) is related to slight mechanical and physical characteristics, such as small differences in pore and particle sizes. The proposed device features a pore size slightly lower than that available in the primary predicate device. However, a reference predicate is provided which features a range of pore sizes capturing those of the proposed device. Similarly, the proposed device features particle size which is slightly lower than that of the primary predicate. However, additional nonclinical testing results demonstrate that the any differences noted between OSTEON III and its predicate devices do not raise new concerns.

9. Conclusion

Based on the information provided in this premarket notification of GENOSS Co., Ltd. conclude that OSTEON III is substantially equivalent to its predicate devices.