MAY 2 2 2014

K123876

510(k) Summary

1. **510(k) Owner**

Odontit SA
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Argentina
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Email: info@odontit.com

2. **Company Contact**

Mario Gersberg
President

3. **510(k) Preparer**

Blix Winston
ACMD Consulting, LLC.
Mullinix Mill Road
Mt Airy, MD 21771
USA
Ph: 301-607-9185
Email: fblixwinston@aol.com

4. **Date of Preparation**

May 19, 2014

5. **Device Name and Classification:**

Trade Name:	Synergy
Common Name:	Anorganic Bovine Bone Grafting Material
Classification Name:	Bone Grafting Material, Animal Source

6. **Predicate Devices:**

Device:	Bio-Oss® natural bone grafting material
510 (k) Numbers:	K871773, K952617, K970321, K033815
Manufactured by:	Geistlich Pharma AG Bahnhofstrasse 40 CH-61 10 Wolhusen Switzerland

Device:	Equimatrix™
510 (k) Number:	K11816
Manufactured by:	Luitpold Pharmaceuticals, Inc. One Luitpold Drive, P0 Box 9001SE29Q1 Shirley, NY 11967SE29 Ph: 610-650-4200

7. **Classification Names and Citations:**
   21CFR872.3930, NPM-bone grafting material, animal source, Class II

8. **Compliance with Performance Standards:**
   The Device complies with the requirements listed in Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices

9. **Device Description:**

   a. **General:**
   Synergy is a Xenograft of bovine origin. It contains macro and micro porous structures similar to Bio-Oss. Synergy is a purified osteoconductive mineral structure produced from bone in a multi-stage purification process. Synergy is chemically as well as structurally comparable to mineralized Bio Oss and Equimatrix. Synergy is used as an adjunctive therapy in restoring bony defects in the mouth

   b. **Intended Use:**

   SYNERGY is intended for use in:

   - Augmentation or reconstructive treatment of alveolar ridge
   - Filling periodontal defects
   - Filling defects after root resection, apicoectomy, and cystectomy
   - Filling extraction sockets to enhance preservation of the alveolar ridge
   - Elevation of maxillary sinus floor
   - Filling periodontal defects in conjunction with products intended for Guided Tissue
   - Regeneration (GTR) and Guided Bone Regeneration (GBR).
   - Filling peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

c. Features:

Synergy is produced from selected bovine bone. Physical and chemical analysis has demonstrated that the composition of Synergy is similar to the predicate devices which have been shown to be anorganic, osteoconductive hydroxyapatite bone mineral. The product is milled to generate granules of two sizes (0.30 – 0. 84 mm or 0.84 – 2.0 mm) which are put into glass vials and sterilized by gamma irradiation.

d. Working Principle:

Synergy has porous structure and composition, encouraging the formation and ingrowth of new bone at the implantation. In the course of time Synergy is partially remodelled by osteoclasts and osteoblasts (physiological remodelling).

e. **Device Comparison Table:**

Descriptive Information	**Synergy**	**Bio-OSS**	**EQUIMATRIX™**
510(k) Number	N/A	K871773, K952617, K970321, K033815	K111816
Intended Use	SYNERGY is intended for use in: • Augmentation or reconstructive treatment of alveolar ridge • Filling periodontal defects • Filling defects after root resection, apicoectomy, and cystectomy • Filling extraction sockets to enhance preservation of the alveolar ridge • Elevation of maxillary sinus floor • Filling periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR). • Filling peri-implant defects in	Bio-Oss® is recommended for: • Augmentation or reconstructive treatment of the alveolar ridge. • Filling of intra bony periodontal defects. • Filling of defects after root resection, apicoectomy, and cystectomy. • Filling of extraction sockets to enhance preservation of the alveolar ridge. • Elevation of the maxillary sinus floor. • Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).	EQUIMATRIX™ cancellous and cortical granules are recommended for: • Augmentation or reconstructive treatment of the alveolar ridge. • Filling of infrabony periodontal defects. • Filling of defects after root resection, apicoectomy, and cystectomy. • Filling of extraction sockets to enhance preservation of the alveolar ridge. • Elevation of the maxillary sinus floor. • Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration(GBR). • Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

	conjunction with products intended for Guided Bone Regeneration (GBR)	• Filling of peri-implant defects inconjunction with products intended for Guided Bone Regeneration (GBR). Bio-Oss® blocks are recommended for: • Filling of large oral and maxillofacial osseous cavities.	
Descriptive Information	**Synergy**	**Bio-Oss**	**EQUIMATRIX™**
Device Design			
Form	0.30 – 0. 84 mm or 0.84 – 2.0 mm granules	0.2 mm to 1.0 mm or 1.00mm to 2.00mm granules	0.2 mm to 1.0 mm or 1.00mm to 2.00mm granules
		Bio-Oss Cancellous- Bone Block Block Size1 x 1 x 2 c m	N/A
Source Bone	Bovine	Bovine	Equine
Supplied as	Granules supplied in single use sterilized vial.	Granules supplied single use sterilized vial	Granules supplied as single use sterilized screw cap container or prefilled syringe
Descriptive Information	**Synergy**	**Bio-Oss**	**EQUIMATRIX™**
Device Design			
Material	Anorganic osteoconductive hydroxyapatite bone mineral	Anorganic naturally derived osteoconductive hydroxyapatite bone mineral	Anorganic naturally derived osteoconductive hydroxyapatite bone mineral
Sterilization	Gamma irradiation	Gamma Irradiation	Gamma irradiation

Descriptive Information	Synergy	Bio-Oss	EQUIMATRIX™
Device Design			
Shelf Life	1 year	Manufacturer	3 Years
Calcium/Phosphorous (Ca/P Ratio)	2.1 / 1	1.66 / 1	Similar to BioOss

f. Substantial Equivalence

Based upon comparison of the intended use, biocompatibility, sterility, physical and chemical testing, and the performance evaluation of the subject and predicate device in an anatomically relevant animal model, and the results of clinical cases, Odontit SA concludes that Synergy is substantially equivalent to the predicate devices Bio-Oss and Equimatrix™.

g. Standards

Synergy complies with the standards listed below:

FDA Recognized Standards	Synergy	Bio-Oss	EQUIMATRIX
	ISO 10993	ISO 10993	ISO 10993
	ASTM F1088 - 04a		
Additional Standards Used	**Synergy**	**Bio-Oss**	**EQUIMATRIX**
	USP 31		
	ASTM F1185 - 03		
	ASTM F1581 - 08		
	Argentine Pharmacopeia		
FDA Special Controls	**Synergy**	**Bio-Oss**	**Equimatrix™**
	Class II Special Control Guidance Bone Grafting Material Devices	Class II Special Control Guidance Bone Grafting Material Devices	Class II Special Control Guidance Bone Grafting Material Devices

h. Conclusion:

Based on the information provided within this submission, Odontit concludes that Synergy is substantial equivalent to Bio-Oss and Equimatrix™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 22, 2014

Odontit SA
C/O Mr. Blix Winston, MPA, MS
Submission Correspondent
ACMD Consulting, Limited Liability Company
2600 Mullinix Mill Road
Mt. Airy, MD 21771

Re: K123876
Trade/Device Name: Synergy
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material, Animal Source
Regulatory Class: II
Product Code: NPM
Dated: May 19, 2014
Received: May 19, 2014

Dear Mr. Winston:

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 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. 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,

Mary S. Runner -S

Erin I. Keith, M.S.
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K123876

Device Name
Synergy, Anorganic Cancellous Bovine Bone Graft Material

Indications for Use *(Describe)*

SYNERGY is intended for use in:
Augmentation or reconstructive treatment of alveolar ridge
Filling periodontal defects
Filling defects after root resection, apicoectomy, and cystectomy
Filling extraction sockets to enhance preservation of the alveolar ridge
Elevation of maxillary sinus floor
Filling periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
Filling peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sheena A. Green -S
2014.05.21 14:36:28 -04'00'

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