1 of 5

2.0 510(k) Summary

K111816

Sponsor/Applicant

Luitpold Pharmaceuticals, Inc.
One Luitpold Drive, PO Box 9001
Shirley, NY 11967
Phone: 610.650.4200
Fax: 610.650.0114
Contact: Marsha E. Simon

SEP 2 9 2011

Date Prepared: June 23, 2011

Device Name and Identification

Proprietary Name: EquiMatrix™

Common/Usual Name: Natural Bone Mineral Matrix
Anorganic Equine Bone Grafting Material

Classification Name: Bone Grafting Material
Animal Source Dental Bone Grafting Material

Predicate Device

Bio-Oss® natural bone grafting material (K871773, K952617, K970321, K033815)
Manufactured by:
Geistlich Pharma AG
Bahnhofstrasse 40
CH-6110 Wolhusen
Switzerland

Device Category/Class

Device Class: Class II
Regulation Number: 21 C.F.R. 872.3930
Product Code: NPM

K111816

Intended Use

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).

Device Description

EquiMatrix™ is a sterile, natural, non-antigenic, porous bone mineral matrix produced by the removal of organic compounds from equine bone. Due to its natural structure EquiMatrix™ is physically and chemically comparable to the mineralized matrix of human bone. The anorganic bone matrix of EquiMatrix™ has a macro and microporous structure similar to human bone. The formation and in-growth of new bone at the implantation site of EquiMatrix™ is favored due to its trabecular architecture, interconnecting macro and micro pores, and its natural consistency. It is supplied as cancellous (spongiosa) or cortical granules in a single use container, packaged in a secondary thermoform blister, and sterilized by γ-irradiation.

Technological Aspects of Particulate Bone Grafting

Particulate bone grafts (cancellous and cortical) are widely used in dentistry for the treatment of periodontal bone defects, prevention of alveolar resorption following tooth extraction, and to augment deficient and atrophic sites prior to implant placement.

Although autogenous tissue has been traditionally regarded as the gold standard for bone regeneration, it has the disadvantage of limited availability, increased patient morbidity, and irregular resorptive patterns. Therefore, other sources of graft material including allogenic, alloplastic, and xenogenic particles have been developed and studied as an osteoconductive matrix for new bone formation.

Xenografts of bovine origin have proven to be especially useful for guided bone regeneration in stabilizing the blot clot, promoting revascularization and maintaining space during wound healing. There is also an inherent advantage in these xenografts for sinus augmentation and in the aesthetic zone as a foundation for implant and dental reconstruction due to the slower resorption rate.

K111816

Equimatrix is a particulate natural bone mineral derived from horses which is proposed as an alternative xenograft material for use where dental bone grafting is required for treatment of periodontal defects and implant site development.

Basis for Substantial Equivalence

EquiMatrix™ and Bio-Oss® have a similar physical and chemical structure. Both are porous, biocompatible bone grafts that facilitate the formation and mineralization of new bone by the osteoblast. The primary difference between the two products is the source bone: EquiMatrix™ is manufactured from equine (horse) bones, while Bio-Oss® is manufactured from bovine (cows) source material.

The following table summarizes the basis for the Sponsor's substantial equivalence determination:

Table 1 Substantial Equivalence Comparison

Item	EquiMatrix™	Bio-Oss®
Intended use	Used as an adjunctive therapy in restoring bony defects	Used as an adjunctive therapy in restoring bony defects
Target population	Human oral, periodontal	Human oral, periodontal
Dosage form	Granules contained in single use container	Granules contained in single use container
Granule sizes	0.2 mm to 1.0 mm or 1.0 mm to 2.0 mm granules	0.25 mm to 1.0 mm or 1.0 mm to 2.0 mm granules
Material	Anorganic naturally derived osteoconductive hydroxyapatite bone mineral	Anorganic naturally derived osteoconductive hydroxyapatite bone mineral

4875

K111816

Table 1 (continued)

Item	EquiMatrix™	Bio-Oss®
Source bone	Equine bone	Bovine bone
Physical Morphology	Trabecular, interconnecting macro and micro pores	Trabecular, interconnecting macro and micro pores
Biocompatibility	Biocompatible, as demonstrated by: - Genotoxicity testing - Intracutaneous reactivity testing - Maximization and sensitization testing - Pyrogen testing - Acute systemic injection testing - Cytotoxicity testing - Implantation testing - Preclinical safety and efficacy testing - Clinical case series	Biocompatible (as demonstrated in published literature)
Performance	Bone formation	Bone formation
Compatibility w/other devices	Can be used with GTR membrane	Can be used with GTR membrane
Sterilization Process	Sterile by Gamma irradiation	Sterile by Gamma irradiation
Chemical Composition	Similar to Bio-Oss® based on chemical analyses, XRD, FT-IR, and ICP analysis	Similar to EquiMatrix™ based on chemical analyses, XRD, FT-IR, and ICP analysis
Chemical safety	Biocompatible	Biocompatible
Anatomical sites	Oral, Periodontal	Oral, Periodontal
Pyrogen Free	Yes	Yes
Shelf life	3 years	Determined by Manufacturer

Brief Summary of Data Submitted in Support of Effectiveness

The Sponsor evaluated the performance characteristics of EquiMatrix™ and Bio-Oss® with a thorough chemical and physical characterization. The physical and chemical characteristics of the products were found to be comparable. Further,

in several animal studies, both products were found to grow new bone and be subsequently resorbed at similar rates. Finally, in a clinical case series, use of EquiMatrix™ resulted in defect healing and formation of new bone of sufficient quality to obtain dental implant placement.

Brief Summary of Data Submitted in Support of Safety

EquiMatrix™ was the subject of the full range of biocompatibility tests recommended in the FDA's "Class II Special Controls Guidance Document: Dental Bone Grafting Devices" and in accordance with ISO 10993. Test results confirmed product safety. Organic material has been removed from the product, and product specifications have been established to limit protein content. Further, the product is sterilized to achieve a sterility assurance level SAL 1×10^{-6}.

Based on the information presented herein, it has been demonstrated that EquiMatrix™ is substantially equivalent to Bio-Oss®, and safe and effective for the proposed 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

Ms. Marsha Simon
Manager, Regulatory Affairs
Luitpold Pharmaceuticals, Incorporated
One Luitpold Drive
P.O. Box 9001
Shirley, New York 11967

SEP 29 2011

Re: K111816
Trade/Device Name: EquiMatrix™ Natural Bone Mineral Matrix
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPM
Dated: September 23, 2011
Received: September 26, 2011

Dear Ms. Simon:

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

K111816

1061

1.0 Indications for Use Statement

INDICATIONS FOR USE

510(K) Number:
Device Name: EquiMatrix™ Natural Bone Mineral Matrix

INDICATIONS AND USAGE:
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).

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K111816