August 20, 2021

Wishbone SA
Emilie Dory
Operations Manager
1, Rue de 1'Expansion
Flemalle, Liege 4400
BELGIUM

Re: K211551
Trade/Device Name: Wishbone HA
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: NPM
Dated: June 7, 2021
Received: June 8, 2021

Dear Emilie Dory:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Andrew Steen
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Wishbone HA

Indications for Use *(Describe)*
Wishbone HA is intended for the following uses:
• Filling of infrabony periodontal defects;
• Filling of periodontal defects in conjunction with products intended for guided tissue regeneration and guided bone regeneration;
• Filling of defects after root resection, apicectomy and cystectomy;
• Filling of extraction sockets to enhance preservation of the alveolar ridge;
• Augmentation or reconstructive treatment of the alveolar ridge;
• Elevation of the maxillary sinus floor;
• Filling of peri-implant defects in conjunction with products intended for guided bone regeneration.

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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510(k) Summary

1. SUBMITTER

Submitter Name:	Wishbone SA
Submitter Address:	1, Rue de l'Expansion, 4400 Flémalle - Belgium
Phone Number:	+32484706172
Contact Person:	Emilie Dory
Date Prepared:	20 August 2021

2. DEVICE

Device Trade Name:	Wishbone HA
Common Name:	Bone graft material
Classification Name, Number & Product Code: Class: Classification Panel:	Bone grafting material 21 CFR 872.3930 NPM II Dental

3. PREDICATE DEVICE

Primary Predicate Device:	K122894, Geistlich Bio-Oss, Geistlich Pharma AG

4. REFERENCE DEVICE

Reference Device:	No reference device was used in this submission

5. DEVICE DESCRIPTION

Wishbone HA is a xenograft biomaterial composed of deproteinized hydroxyapatite from bovine origin. It is intended to fill, augment, or reconstruct periodontal defects and/or bony defects of the upper or lower jaw.

Wishbone HA is supplied as a mix of cancellous and cortical particles (particles size 0.25 to 1.0 mm) in a single use thermoformed blister, packaged in a secondary thermoformed blister and sterilized by gamma irradiation.

The device is intended to be used in medical procedures, by a qualified physician (academically trained dentists, periodontists and oral surgeons).

6. INDICATIONS FOR USE

Wishbone HA is intended for the following uses:

- Filling of infrabony periodontal defects
- Filling of periodontal defects in conjunction with products intended for guided tissue regeneration and guided bone regeneration
- Filling of defects after root resection, apicectomy and cystectomy
- Filling of extraction sockets to enhance preservation of the alveolar ridge
- Augmentation or reconstructive treatment of the alveolar ridge
- Elevation of the maxillary sinus floor
- Filling of peri-implant defects in conjunction with products intended for guided bone regeneration.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

Table 1: Comparison of new device to predicate device

	New Device	**Primary Predicate Device**
Device name	Wishbone HA	Geistlich Bio-Oss
510(k) Number	K211551	K122894
Manufacturer	Wishbone SA	Geistlich Pharma AG
Regulation Number	872.3930	872.3930
Device Classification Name	Bone grafting material	Bone grafting material
Product Code	NPM	NPM
Intended Use/ Indications for use	• Filling of infrabony periodontal defects; • Filling of periodontal defects in conjunction with products intended for guided tissue regeneration and guided bone regeneration; • Filling of defects after root resection, apicectomy and cystectomy; • Filling of extraction sockets to enhance preservation of the alveolar ridge; • Augmentation or reconstructive treatment of the alveolar ridge • Elevation of the maxillary sinus floor; • Filling of peri-implant defects in conjunction with products intended for guided bone regeneration.	- 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); and - Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).
Intended patient population	Adults	Adults
Mode of action	Conductive bone graft	Conductive bone graft

Anatomical sites	Oral, Periodontal	Oral, Periodontal
Environment of use	Wishbone HA should only be used by trained dentists, periodontists or oral surgeons.	Geistlich Bio-Oss® should only be used by trained dentists or oral surgeons.
Sterilization	Gamma irradiation	Gamma irradiation
Reusability	Single use only	Single use only
Pyrogenicity	Non-pyrogenic	Non-pyrogenic
Packaging	Wishbone HA particles are packaged in a single use thermoformed PETG (Polyethylene Terephthalate Glycol) blister (primary packaging) hermetically sealed with a Tyvek®. This package is placed in a secondary thermoformed.	Double sterile barrier system consisting of a glass vial and an outer blister.
Source of materials	Bovine	Bovine
Chemical Composition	Calcium: 30 - 40 % (w./w.) Phosphorous: 15 - 20 % (w./w.) Sodium: 0.0 - 1.0 % (w./w.) Magnesium: 0.0 - 1.0 % (w./w.) Summed up to 100% by mass: – Hydroxyapatite $Ca_5(PO_4)_3OH$ (CAS® 1306-06-5): ≥97% – $CaCO_3$ (CAS® 471-34-1) – MgO* (CAS® 1309-48-4): ≤2% – H_2O (CAS ® 7732-18-5): ≤1% – Organic compounds: 0%	From the original 510(k): Calcium: 35% - 40% (w./w.) Phosphorous: 13.5% - 18.5% (w./w.) Summed up to 100% by mass**: – Hydroxyapatite (Pentacalciumhydroxy-[tri]-phosphate $Ca_5(PO_4)_3(OH)$) (93.6%), – Calcium carbonate (CaO_3) (3,4%) – Water (3%) – No organic components (0%)
Crystalline phases	Hydroxyapatite > 95%	Hydroxyapatite
Dosage form	Mix of cancellous and cortical granules	Cancellous granules or porous block
Particle sizes	0.25 - 1.0 mm	0.25 - 1.0 mm (small particles) 1.0 - 2.0 mm (large particles)
Product size (g)	0.25, 0.5, 1.0, 2.0	0.25, 0.5, 2.0, 5.0 (0.25-1.0 mm) 0.5, 2.0 (1.0-2.0 mm) For blocks: 1 X 1 X 2 cm (approx.)

Biocompatibility testing	Chemical characterization Toxicological evaluation Cytotoxicity Sensitization Intracutaneous Reactivity/Irritation Acute Systemic Toxicity Material Mediated Pyrogenicity Genotoxicity Implantation	Per ISO 10993-1 for the intended use

* Wishbone HA is composed of only bovine bone without any added components. The magnesium oxide (MgO) is not added to Wishbone HA but rather naturally appears during the sintering process in the form of magnesium oxide crystals.

** Data taken from 510(k) summary of Straumann® Cerabone® (K173594) which uses K122894 Geistlich Bio-Oss as the predicate device.

Equivalences:

The intended use is the same, and the technological characteristics are essentially the same as those of the predicate, K122894, Geistlich Bio-Oss. Both devices are made of deproteinized hydroxyapatite from bovine origin, intended to be implemented as a bone graft matrix in periodontal or bony defects. Both devices are intended to be used by dental health care professionals (e.g. dentists, periodontists and oral surgeons). Both devices are intended for single patient use and sterilized by gamma irradiation.

Differences that are demonstrated to be substantially equivalent:

As indicated in Table 1 above, several differences with respect to technological characteristics were identified between Wishbone HA and the primary predicate, namely the chemical composition, crystalline phases, dosage form, specific surface area and the packaging configuration.

Performance testing was conducted to demonstrate substantial equivalence of Wishbone HA to the predicate device. The test results are summarized below.

8. PERFORMANCE DATA

Non-Clinical bench testing	Wishbone HA was the subject of the full range of physical and chemical characterization tests recommended in the FDA's "Class II Special Controls Guidance Documents: Dental Bone Grafting Devices". These bench tests included chemical analysis, phase composition analysis, protein and organic content analysis, morphology analysis, porosity analysis, pH analysis, dissolution analysis and mechanical evaluation.

Non-Clinical animal performance Testing

A pre-clinical GLP study was performed in canine mandibular defect model system in Beagle dogs to evaluate the in-vivo performance of the Wishbone HA. In this study the local effects of implantation of Wishbone HA in the target locations, as well as bone growth, at subchronic time-points (4, 12 and 26 weeks) were evaluated.

By all parameters assessed at the 26 weeks time-point of the study, biocompatibility and regeneration of defects treated with Wishbone HA showed similar results to defects treated with the predicate device, Bio-Oss®.

Biocompatibility

Wishbone HA was the subject of a range of biocompatibility tests in accordance with ISO 10993 series. Test results confirmed that Wishbone HA is biocompatible for the stated intended use.

Animal tissue

The methods of sourcing, collection and handling of the bovine-derived bones were assessed to demonstrate compliance with relevant requirements of ISO 22442 series and FDA guidance (2019). Wishbone HA is provided free from organic residues. Protein content is routinely controlled during the production process. The manufacturing process includes several steps intended to inactivate viruses. The results of the viral inactivation studies showed that the raw material and device manufacturing processes of the Wishbone HA are capable of achieving at least a 6-log viral reduction of selected model viruses which were tested.

Sterilization and shelf life

Wishbone HA is provided sterile and is intended for single patient use only. Wishbone HA is sterilized with gamma irradiation to meet a minimum sterility assurance level (SAL) of 10^{-6}. Validation of the sterilization dose was conducted following VD_{max} method.

Shelf life study supports a shelf life of 36 months for Wishbone HA when stored under the recommended environmental conditions. The shelf life studies confirmed that the packaging maintains the integrity of the device and its sterility throughout the shelf life of the device.

Validation studies for sterilization, packaging and shelf life conform to the following standards:

Standard reference	Standard title
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11137-1:2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
EN ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Part 3: Guidance on dosimetric aspects of development, validation and routine control
EN ISO 11737-1:2018	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2009	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN 868-5:2009	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
ASTM F88F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886F1886M-16	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
ASTM F1980-16	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
ASTM D642-15	Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads
ASTM D6344-04 (2017)	Standard Test Method for Concentrated Impacts to Transport Packages
ASTM D999-08 (2015)	Standard Test Methods for Vibration Testing of Shipping Containers
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D4332-14	Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
ASTM D4728-17	Standard Test Method for Random Vibration Testing of Shipping Containers

ASTM D5276-98 (2017)	Standard Test Method for Drop Test of Loaded Containers by Free Fall
EN ISO 11140-1:2014	Sterilization of health care products - Chemical indicators - Part 1: General requirements

9. CONCLUSION

The information discussed above and provided in the 510(k) submission demonstrate that the Wishbone HA is substantially equivalent to the predicate.