December 23, 2024

Noraker
% Elisa Maldonado-Holmertz
RA/QA Consultant
Obelix Consulting
806 Jefferson Street
Bastrop, Texas 78602

Re: K242782
Trade/Device Name: GlassBone Granules
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: November 12, 2024
Received: November 13, 2024

Dear Ms. Maldonado-Holmertz:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSE MUIR -S Digitally signed by JESSE MUIR -S
Date: 2024.12.23 09:42:12 -05'00'

Jesse Muir, Ph.D.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242782

Device Name

GlassBone Granules

Indications for Use *(Describe)*

GlassBone Granules is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. GlassBone Granules resorbs and is replaced with bone during the healing process.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

SUBMITTER

Submission Sponsor:
Catherine FLACARD
Compliance & Innovation Chief Officer
Noraker, SAS
60, Avenue Rockefeller
69008 Lyon
France
Email: c.flacard@noraker.com
Tel number: +33 (0)4 78 93 30 92

Submission Correspondent:
Elisa Maldonado-Holmertz
RA/QA Consultant
Obelix Consulting, LLC
806 Jefferson St
Bastrop, TX 78602
USA
Email: elisamh@obelixconsult.com
Tel number: +1 512 431 6069

Date Prepared: 13 September 2024

SUBJECT DEVICE
Name of Device: GlassBone Granules
Common or Usual Name: Filler, Bone Void, Calcium Compound
Classification Name: Resorbable calcium salt bone void filler device (21 CFR 888.3045)
Regulatory Class: Class II
Product Code: MQV

PREDICATE DEVICE
BonAlive Granules - K231528

This predicate has not been subject to a design-related recall.

REFERENCE DEVICE
NovaBone Resorbable Bone Graft Substitute - K052494
This predicate has not been subject to a design-related recall.

DEVICE DESCRIPTION
GlassBone Granules is a synthetic and biocompatible bone substitute device (bioactive glass 45S5). GlassBone Granules is composed by weight of 45S5 bioactive glass granules (45% SiO_2, 6% P_2O_5, 24.5% CaO and 24.5% Na_2O).
It is sterilized with gamma irradiation and is single use and is available in different unit sizes.

INDICATIONS FOR USE

GlassBone Granules is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. GlassBone Granules resorbs and is replaced with bone during the healing process.

Rx only.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE
GlassBone Granules is substantially equivalent to the following predicate and reference device:

Manufacturer	**Subject Device** Noraker SAS	**Primary predicate** BonAlive Biomaterials, Ltd	**Reference Device** NovaBone	**SIGNIFICANT DIFFERENCES**
Trade Name	GlassBone® Granules	BonAlive® Granules	Resorbable Bone Graft Substitute (Particulate)	None
510(k) Number	-	K231528	K052494	-
Product Code	MQV	MQV	MQV	None
Regulation Number	888.3045	888.3045	888.3045	None
Regulation Name	Resorbable calcium salt bone void filler device	Resorbable calcium salt bone void filler device	Resorbable calcium salt bone void filler device	None
Indications for Use	GlassBone Granules is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities	Bonalive® Orthopedics granules is an implant intended to fill bony voids or gaps of the skeletal system (i.e.,	NovaBone Resorbable Bone graft substitute is indicated only for bony	None

Manufacturer	**Subject Device** Noraker SAS	**Primary predicate** BonAlive Biomaterials, Ltd	**Reference Device** NovaBone	**SIGNIFICANT DIFFERENCES**
Trade Name	GlassBone® Granules	BonAlive® Granules	Resorbable Bone Graft Substitute (Particulate)	None
	and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. GlassBone Granules resorbs and is replaced with bone during the healing process.	extremities and pelvis). These osseous defects may be the result of benign bone cysts and tumors (in adults and pediatric patients ≥ 6 years old), are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. Bonalive® Orthopedics granules resorbs and is replaced with bone during the healing process.	voids or gaps that are not intrinsic to the stability of the bony structure. NovaBone is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.	
Rx or OTC	Rx	Rx	Rx	None
Physical Form	Amorphous, non-porous random-shaped particles	Amorphous, non-porous random-shaped particles	Amorphous, non-porous random-shaped particles	None
Color	Brown	Brown	White	None
Materials Composition	Bioactive glass 45S5 Bioglass (SiO_2, P_2O_5, CaO and Na_2O	Bioactive glass S53P4 glass (SiO_2, P_2O_5, CaO and Na_2O)	Bioactive glass 45S5 Bioglass (SiO_2, P_2O_5, CaO and Na_2O)	None
Product Sizes	Granule sizes: 0.5-1mm 1-3mm Product volumes: 0.5cc 1 cc 5 cc 10 cc 16 cc	Granule sizes: 0.5-0.8 mm 1.0-2.0 mm Product volumes: 1 cc 2.5 cc 5 cc 10 cc	Granule sizes: 90-710µm Product volumes: 2 cc 5 cc 10 cc 15 cc	Similar without affecting safety or effectiveness
Biocompatibility	Biocompatible ISO 10993	Biocompatible ISO 10993	Biocompatible ISO 10993	None
Sterilization	Gamma, SAL 10^{-6}	Gamma, SAL 10^{-6}	EtO, SAL 10^{-6}	None
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	Non-pyrogenic	None
Single Use/ Reuse	Single use only	Single use only	Single use only	None
Mode of action	Works by leaching ions that react with the body fluids transforming the glass surface chemically into one that by its chemical composition and structure resembles the mineral phase found in natural bone.	Works by leaching ions that react with the body fluids transforming the glass surface chemically into one that by its chemical composition and structure resembles the mineral phase found in natural bone.	Works by leaching ions that react with the body fluids transforming the glass surface chemically into one that by its chemical composition and structure resembles the mineral phase found in natural bone.	None

Manufacturer	**Subject Device** Noraker SAS	**Primary predicate** BonAlive Biomaterials, Ltd	**Reference Device** NovaBone	**SIGNIFICANT DIFFERENCES**
Trade Name	GlassBone® Granules	BonAlive® Granules	Resorbable Bone Graft Substitute (Particulate)	None
Properties	Synthetic Osteoconductive	Synthetic Osteoconductive	Synthetic Osteoconductive	None
MR safety	MR Safe	MR Safe	Unknown	None

NON CLINICAL PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Bench testing:

Bench testing was conducted according to FDA Guidance "Resorbable Calcium Salt Bone Void Filler Device - Class II Special Controls Guidance Document for Industry and FDA Staff" and ASTM F1538.

- pH
- Solubility
- Apatite
- Composition – Heavy Metals
- Crystallinity
- Particle Size
- Surface Area

Animal testing and biocompatibility:

Biocompatibility testing was conducted in accordance with ISO-10993-1, "Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process".

- Physico-chemical characterization
- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity
- Material mediated pyrogenicity
- Acute systemic toxicity
- Local effects of implantation
- Genotoxicity

Sterility and Shelf Life
The following testing was performed on GlassBone Granules:

- ISO 11137 – Radiation Sterilization Validation
- ISO 11607 - Packaging for terminally sterilized medical devices

Clinical Performance Data
There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device.

Statement of Substantial Equivalence
Noraker GlassBone Granules is substantially equivalent to the predicate device when comparing the following characteristics:
•Indications for Use
•Principles of Use
•Fundamental Technology
•Basic Design
•Materials Used
•Where used
•Standards met
•Sterilization Method

GlassBone Granules meet all requirements for overall design and confirms that the output meets the design inputs and specifications. The GlassBone Granules passed all testing stated above as shown by acceptable results obtained.

GlassBone Granules complies with the applicable voluntary, national, and international standards and guidance.

Noraker, SAS believes that the bench and non-clinical performance data supports the safety of GlassBone Granules, and the device should perform effectively as intended in the specified use conditions. The non-clinical performance data demonstrates that GlassBone Granules performs comparably to the predicate device that is currently marketed for the same intended use and presents no new concerns about safety and effectiveness.