Bonalive , Ltd.
% Elisa Maldonado-Holmertz
RA/QA Consultant
Obelix Consulting
806 Jefferson St.
Bastrop, Texas 78602

May 14, 2026

Re: K253883
Trade/Device Name: Bonalive Maxillofacial
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: LYC
Dated: April 9, 2026
Received: April 13, 2026

Dear Elisa 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253883

Device Name
Bonalive® Maxillofacial

Indications for Use *(Describe)*
Bonalive® Maxillofacial is a sterile medical device consisting of bioactive glass. Bioactive glass is a bone grafting material that is intended to fill, augment or reconstruct bony defects. Bonalive® Maxillofacial is indicated for use in the maxillofacial area.

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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Special 510(k) Summary
K253883

1. Submission Sponsor

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3. Date Prepared

11 May 2026

4. Device Identification

Type of 510(k) Submission:	Special 510(k)
Trade or Proprietary Name:	Bonalive® Maxillofacial
Device Description:	Bone grafting material, synthetic
Regulation Classification:	872.3930
Product Code:	LYC
Class of Device:	Class II
Review Panel:	Dental

Reason for Submission:	Process Change (Sterilization), Packaging Change (applicator, sterile barrier) and Labeling Change (Company Name, Product Name, Removal of "cranio" from indication for use).
Predicate:	K070055 Bonalive Granules and Bonalive Plates by Vivoxid Ltd.
Prior Related Submission:	K191274 Bonalive Granules (Exact same device as the subject device however, different product code and indication for use)
Multiple Devices:	None; this is the only device in this submission

5. Legally Marketed Predicate Device(s)

Predicate: K070055 Bonalive Granules and Bonalive Plates by Vivoxid Ltd.
Reference: K191274 BonAlive Granules by Bonalive Biomaterials, Ltd.

6. Device Description

Bonalive® Maxillofacial is composed of calcium-phosphorous-sodium-silicate (glass S53P4) granules and is a sterile medical device. This synthetic, osteoconductive material is comprised of SiO_2, Na_2O, CaO and P_2O_5. Bioactive glass is characterized by its ability to attach firmly to living tissue. Other properties include its ability to facilitate bone tissue growth, bond chemically with surrounding bone, and promote new bone formation in the implanted area.

In aqueous solution (e.g. body fluids), bioactive glass works by leaching out ions and developing a silica-gel layer which acts as a template for a calcium phosphate (CaP) precipitation. The CaP crystallizes to hydroxyapatite, which resembles the mineral phase of natural bone in its chemical composition and structure, thus enabling bonding of the bioactive glass to the surrounding bone.

Bonalive® Maxillofacial resorb and is slowly replaced with bone over a period of years. Bonalive® Maxillofacial is radiodense thus enabling postoperative radiologic evaluation.

Best results are obtained by ensuring close contact of the device with surrounding bone tissue and by carefully following the Instructions for Use.

Bonalive® Maxillofacial is sterilized by irradiation and is available in different granule and unit sizes.

7. Indication for Use Statement

Bonalive® Maxillofacial is a sterile medical device consisting of bioactive glass. Bioactive glass is a bone grafting material that is intended to fill, augment or reconstruct bony defects. Bonalive® Maxillofacial is indicated for use in the maxillofacial area.

For Rx Use

8. Substantial Equivalence Discussion

The following table compares the subject device to the predicate with respect to intended use, technological characteristics, and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table – Comparison of Characteristics

Manufacturer	**SUBJECT** Bonalive Ltd	**PREDICATE** Vivoxid Ltd (now called Bonalive Ltd)	**SIGNIFICANT DIFFERENCES**
Trade Name	Bonalive® Maxillofacial	Bonalive Granules and Bonalive Plates	
510(k) Number	K253883	K070055	NA
Product Code	LYC	LYC	None
Regulation Number	872.3930	872.3930	None
Device Name	Bone grafting material, synthetic	Bone grafting material, synthetic	None
Indications for Use	Bonalive® Maxillofacial is a sterile medical device consisting of bioactive glass. Bioactive glass is a bone grafting material that is intended to fill, augment or reconstruct bony defects. Bonalive® Maxillofacial is indicated for use in the maxillofacial area.	BonAlive™ Granules are sterile medical devices consisting of bioactive glass. Bioactive glass is a bone grafting material that is intended to fill, augment or reconstruct periodontal or bony defects. BonAliveTM Granules are indicated for use in the craniomaxillofacial area including jaws.	Removal of “cranio”. Dental bone grafting materials are not indicated for anatomical regions outside the maxillofacial region.
Rx or OTC	Rx	Rx	None
Physical Form	Amorphous, non-porous random-shaped particles	Amorphous, non-porous random-shaped particles	None
Color	Brown	Slightly pink	Color is different and does not impact substantial equivalence. The color change is a result of the new sterilization method - dry heat does not elicit a

Manufacturer	**SUBJECT** Bonalive Ltd	**PREDICATE** Vivoxid Ltd (now called Bonalive Ltd)	**SIGNIFICANT DIFFERENCES**
Trade Name	Bonalive® Maxillofacial	Bonalive Granules and Bonalive Plates	
			color change, while gamma irradiation does.
Materials Composition	SiO_2, Na_2O, CaO and P_2O_5	SiO_2, Na_2O, CaO and P_2O_5	None
Product Sizes & Shapes	Granule sizes: 0.5-0.8 mm 1.0-2.0 mm Product volumes: 1 cc 2.5 cc 5 cc 10 cc	Granules sizes: 0.5-0.8 mm 1.0-2.0 2.0-3.15 mm Product volumes: 1 cc 2 cc 4 cc 16 cc	Largest granule size 2.0-3.15 mm is obsolete and does not impact substantial equivalence. Volumes are different and do not impact substantial equivalence.
Biocompatibility	Biocompatible ISO 10993 series Addition of an Applicator	Biocompatible ISO 10993 series	None Biocompatibility of the applicator was assessed by the ISO 10993 series in the reference device K191274. Can be assessed by a well-established method (i.e. ISO 10993 series)
Sterilization	Gamma Sterile, SAL 10^{-6}	Dry Heat	Different Sterilization method. Gamma sterilization validation was performed per the ISO 11137 series in the reference device K191274. Gamma sterilization validation can be assessed by a well-established method (i.e. ISO 11137 series)
Pyrogenicity	Non-pyrogenic	Non-pyrogenic	None
Single Use/	Single use only	Single use only	None

Manufacturer	**SUBJECT** Bonalive Ltd	**PREDICATE** Vivoxid Ltd (now called Bonalive Ltd)	**SIGNIFICANT DIFFERENCES**
Trade Name	Bonalive® Maxillofacial	Bonalive Granules and Bonalive Plates	
Reuse			
Mode of action	Works by leaching out 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 out 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
Properties	Synthetic Osteoconductive	Synthetic Osteoconductive	None
Shelf Life	5 years ISO 11607	3 years ISO 11607	Extended shelf life does not impact substantial equivalence. The method to assess shelf-life is the same as was employed in the predicate. In addition, the 5-year shelf-life was validated in reference device K191274. Shelf life can be assessed by a well-established method (i.e. ISO 11607 series)

Summary
Bonalive® Maxillofacial and the predicate device K070055 Bonalive Granules have the same technological characteristics (i.e., design, material, chemical composition, principle of operation, critical specifications (i.e., crystallinity, porosity, dissolution/solubility)) and the same intended use, with the exclusion of “cranio”.

The Process Change (Gamma sterilization validation assessed by a well-established method, i.e. ISO 11137 series), Packaging Change (Applicator assessed by a well-established method, i.e. ISO

10993 series, and a new sterile barrier) and Labeling Change (Company Name, Product Name, Removal of “cranio” from indication for use, and Extended Shelf Life assessed by a well-established method, i.e. ISO 11607) do not impact substantial equivalence.

9. Statement of Substantial Equivalence

A subject device is substantially equivalent to a predicate device when the subject device has the same intended use (with the deletion of “cranio”) and the same technological characteristics as the previously cleared predicate device, and that the new subject device does not raise different questions regarding its safety and effectiveness as compared to the predicate device. Bonalive® Maxillofacial is substantially equivalent to its predicate.