February 04, 2022

Biocomposites Ltd
Simon Fitzer
Compliance Director
Keele Science Park
Keele, Stafforshire ST5 5NL
United Kingdom

Re: K212721
Trade/Device Name: Genex® Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 13, 2022
Received: January 18, 2022

Dear Mr. Fitzer:

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

Laura C. Rose, 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212721

Device Name
Genex® Bone Graft Substitute

Indications for Use *(Describe)*
INTENDED USE
Genex® Bone Graft Substitute injectable paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process.

• Genex® Bone Graft Substitute is indicated only for bony voids or defects/gaps that are not intrinsic to the stability of the bony structure

• Genex® Bone Graft Substitute is indicated to be gently packed into voids or defects of the skeletal system (ie long bones, extremities, posterolateral spine and pelvis)

• Genex® Bone Graft Substitute resultant paste can be injected, digitally packed into the bone void to cure in situ or moulded into solid implants that are to be gently packed into the defect

• The bony defects or cavities may be surgically created or the result of traumatic injury. Genex® Bone Graft Substitute provides a bone graft substitute that 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:

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*"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

## Genex® Bone Graft Substitute

**Date summary was prepared** 24th January 2022

**Applicant:**
Biocomposites Ltd
Keele Science Park
Keele
Staffordshire
England
ST5 5NL

**Contact Person:**
Miss Kelsey Gomes
Tel: +44 (0) 1782 338580
Email: kjg@biocomposites.com

**Classification Name:** Filler, bone void, calcium compound
**Common/Usual Name:** Bone void filler
**Trade/Proprietary Name:** Genex® Bone Graft Substitute
**Product code:** MVQ (21CFR 888.3045)

**Device Description:**

Genex® Bone Graft Substitute is a simple to use synthetic resorbable material designed to promote regeneration of bone in osseous defects. It degrades into component elements normally found in the body and is highly biocompatible. The kit contains a powder and mixing solution which, when combined, provides a mouldable cohesive paste. When injected the mixture sets to form Genex® Bone Graft substitute, a hard but resorbable matrix. Genex® Bone Graft Substitute is supplied sterile.
Genex® Bone Graft Substitute, accessories and packaging are not made from natural rubber latex.

**Intended Use / Indications for Use:**
Genex® Bone Graft Substitute injectable paste provides a bone graft substitute that resorbs and is replaced with bone during the healing process

• Genex® Bone Graft Substitute is indicated only for bony voids or defects/gaps that are not intrinsic to the stability of the bony structure
• Genex® Bone Graft Substitute is indicated to be gently packed into voids or defects of the skeletal system (i.e long bones, extremities, posterolateral spine and pelvis)
• Genex® Bone Graft Substitute resultant paste can be injected, digitally packed into the bone void to cure in situ or moulded into solid implants that are to be gently packed into the defect

• The bony defects or cavities may be surgically created or the result of traumatic injury. Genex® Bone Graft Substitute provides a bone graft substitute that resorbs and is replaced with bone during the healing process

**Summary of Technology:**

Genex® Bone Graft Substitute is substantially equivalent to the primary predicate device Genex® (K082381). Technological differences are that the subject device Genex® Bone Graft Substitute is presented as a closed mixing system compared to the predicate device Genex® (K082381). Additional differences between the subject device Genex® Bone Graft Substitute and predicate device (K082381) include the number of syringes supplied and method of mixing.

The technological differences do not raise any concerns regarding safety and effectiveness of the device.

**Non Clinical Testing:**

Data supplied demonstrates that Genex® Bone Graft Substitute is substantially equivalent to the primary predicate device Genex® (K082381) and any differences do not raise any concerns regarding the safety and effectiveness of the device. Bench testing including Biocompatibility testing, Shelf-Life validation studies and Porosity testing have been provided with this submission.

**Substantial Equivalence:**

The indications, contraindications, risks and potential adverse events are the same as identified in the predicate device and are thus substantially equivalent.

Documentation provided demonstrates that the Genex® Bone Graft Substitute is substantially equivalent to the legally marketed predicate device in basic features and intended uses. No new concerns have been identified regarding safety and effectiveness of the subject device.