February 3, 2023

Corliber (Shenzhen) Medical Device Co., Ltd.
℅ Li-Ting Lu
Regulatory Affair
Cosmos Biomed Consulting CO., Ltd
Room 1201, No.1, 188 Alley, Shuangliu Road
Changning District, Shanghai City, China

Re: K220337
Trade/Device Name: GaiaBone™ Bioabsorbable Bone Graft
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 3, 2023
Received: January 3, 2023

Dear Li-Ting Lu:

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,

Laurence D. Coyne -S

Laurence D. Coyne, Ph.D.
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)*
K220337

Device Name
GaiaBoneTM Bioabsorbable Bone Graft

Indications for Use *(Describe)*
GaiaBoneTM Bioabsorbable Bone Graft is an implant intended to fill bony voids or gaps of the skeletal system, i.e., the pelvis and extremities. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. GaiaBoneTM Bioabsorbable Bone Graft 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.

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510(k) SUMMARY

1. Contact Person

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2. Device Name and Classification

Product Name:	GaiaBone™ Bioabsorbable Bone Graft
Classification Name:	Filler, Bone Void, Calcium Compound
Common or Usual Name:	Resorbable calcium salt bone void filler device
Classification Panel:	Orthopedic
Regulation Number:	21 CFR 888.3045
Device Class:	Class II
Product Code:	MQV

3. Predicate Device(s)

Product Name:	Bongold™ Bone Graft Material (K141725)
Classification Name:	Filler, Bone Void, Calcium Compound
Common or Usual Name:	Resorbable calcium salt bone void filler device
Classification Panel:	Orthopedic
Regulation Number:	21 CFR 888.3045
Device Class:	Class II
Product Code:	MQV

4. Device Description

GaiaBone™ Bioabsorbable Bone Graft is a composite of synthetic hydroxyapatite [$Ca_{10}(PO_4)_6(OH)_2$] and lactide-caprolactone copolymer. The composite material is a shapable, absorbable, osteoconductive putty bone graft. It is available in cylinders. This bone graft material contains approximately 50% mineral

by weight. *GaiaBone™ Bioabsorbable Bone Graft* is intended to be used as bone void filler for voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure (i.e., the pelvis, and/or extremities).

GaiaBone™ is easy to be shaped and designed to retain its shape and physical integrity following implantation into a bony site. The product is sterile and for single use only.

5. Intended Use / Indications for Use

GaiaBone™ Bioabsorbable Bone Graft is an implant intended to fill bony voids or gaps of the skeletal system, i.e., the pelvis and extremities. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. *GaiaBone™ Bioabsorbable Bone Graft* resorbs and is replaced with bone during the healing process.

6. Summary of Technological Characteristics

GaiaBone™ Bioabsorbable Bone Graft is a shapable, absorbable, osteoconductive and anti-collapse bone graft in putty form. The product is composed of matrix of hydroxyapatite per ASTM F1185 and lactide-caprolactone copolymer per ASTM F2579.

GaiaBone™ Bioabsorbable Bone Graft provide the same intended use as predicate device with similar composition concept, hydroxyapatite and degradable polymer. *GaiaBone™ Bioabsorbable Bone Graft* is available in three volumes, with the "putty" characteristic derived from its polymer composition, it can be manipulated to fit the bone void like the predicate device according to the instructions provided by IFU.

7. Summary of Non-Clinical Testing to Support Substantial Equivalence

Non-clinical testing performed on the subject device includes tests for: anti-collapse property, *In vitro* degradation, sterilization, product shelf-life and bone defect model in rabbit.

The anti-collapse and degradation property was verified according to clinical requirements. According to the test results, *GaiaBone™ Bioabsorbable Bone Graft* shows comparable performance with the predicate device.

Assessment of biocompatibility of *GaiaBone™ Bioabsorbable Bone Graft* was performed according to ISO 10993-1:2018, demonstrating acceptable biological safety profiles.

Sterilization complies with *ISO 11137, Sterilization of Health Care Products –*

Radiation to ensure a sterility assurance level (SAL) of 10^{-6}. Product shelf-life testing was evaluated to ensure the labeled shelf life.

Bacterial endotoxin testing was performed using the limulus amebocyte lysate (LAL) method. The LAL testing met the limit acceptance criterion of $\leqq 20$ EU/device, based upon the recommendations for implanted devices in the FDA guidance document Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, issued January 21, 2016 (Section V, A, 4).

Results of a rabbit femoral critical defect study demonstrated that after 12 weeks, there was a difference of 5.8% in new bone formation with the GaiaBone™ Bioabsorbable Bone Graft as compared to the empty defect group. The autograft control group demonstrated a difference of 14.5% in new bone formation as compared to the empty defect group. Clinical performance has not been evaluated.

8. Clinical Testing

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

9. Conclusion

GaiaBone™ Bioabsorbable Bone Graft has the same intended use, similar technological characteristics, and principles of operation as the predicate device. The results of the *in vitro* performance characterization, biocompatibility studies, and animal performance study show that the *GaiaBone™ Bioabsorbable Bone Graft* is as safe as the predicate device and substantially equivalent to the predicate device.