October 8, 2021

ACRO Biomedical Co., Ltd.
Dar-Jen Hsieh, CEO
3rd Fl., No. 57, Luke 2nd Rd., Lujhu Dist.
Kaohsiung City, 82151
Taiwan

Re: K212156
Trade/Device Name: ABCcolla® Bone Matrix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: July 12, 2021
Received: July 12, 2021

Dear Dar-Jen Hsieh:

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,

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

Indications for Use Statement

510(K) Number (If Known): K212156

Device Name: ABCcolla® Bone Matrix

Indications for Use: ABCcolla® Bone Matrix is intended to fill bony voids or gaps of skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of bone structure. ABCcolla® Bone Matrix provides resorbs and is replaced by bone during the healing process.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

510(k) Summary

This summary of 510(k) Safety and Effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR 807.92. The assigned 510(k) number is K212156 .

Applicant	ACRO Biomedical Co., Ltd. 3rd Fl., No.57, Luke 2nd Rd., Lujhu Dist., Kaohsiung City 82151, Taiwan Telephone: +886-7-6955-569 Fax: +886-7-6955-069
Contact Person	DAR-JEN HSIEH CEO E mail: dj@acrobiomedical.com
Date of Summary	June 1st, 2021
Name of Device	ABCcolla® Bone Matrix
Common Name	Resorbable Bone Void Filler
Classification	Class II
Regulation Number	21 CFR 888.3045
Product Code	MQV
Advisory Panel	ORTHOPEDIC DEVICES
Predicate Device	• ABCcolla® Bone Graft, K171629 ACRO Biomedical Co., Ltd.
Reference Device	• ORTHOSS® Resorbable Bone Void Filler, K090401 Ed. Geistlich Soehne Ag Für Chemische Industrie

- Bicera™ Resorbable Bone Substitute, K110949
  Wiltrom Corporation Limited
- Geistlich Bio-Oss®, K122894
  Geistlich Pharma Ag

Device Description

ABCcolla® Bone Matrix is a bone mineral matrix of porcine origin. ABCcolla® Bone Matrx is physically and chemically comparable to the mineralized matrix of human bone.

Intended Use

ABCcolla® Bone Matrix is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. ABCcolla® Bone Matrix resorbs and is replaced with bone during the healing process.

Comparison of Technological Characteristics

The subject device is identical to predicate device with respect to materials characteristics, manufacturing, sterilization method, and sterile barrier system.
Since prior clearance of the device, the only change was to add new product specifications for cube or block form.

Characteristic	**ABCcolla® Bone Graft (K171629)**	**ABCcolla® Bone Matrix (subject device)**
Intended Use		
Intended Use	ABCcolla® Bone Graft is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. ABCcolla® Bone	ABCcolla® Bone Matrix is an implant intended to fill bony voids or gaps of the skeletal system (i.e., extremities and pelvis). These osseous defects are surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. ABCcolla® Bone

	Graft resorbs and is replaced with bone during the healing process.	Matrix resorbs and is replaced with bone during the healing process.
Physical characteristics		
Form	Granule and Cube	Granule and Block
Specifications	Maximum volume 5 c.c.	Maximum volume 5 c.c.
Manufacture		
Manufacturing conditions	Same manufacturing conditions	Same manufacturing conditions
Viral inactivation	Same viral inactivation step	Same viral inactivation step
Sterilization	Gamma radiation	Gamma radiation
Packaging	Glass bottle and Tyvek pouch	Glass bottle and Tyvek pouch

Substantial Equivalence Summary

The subject device is made of the same raw materials and manufactured with the same manufacturing process (except for cutting the bone material in different length and/or height to generate the new specifications), hence the material properties are identical.

Further, the same release testing as performed for the predicate is conducted for the subject device and includes determination of appearance, specification (granule size, weight, or dimension), moisture content and sterility test. The predicate and subject devices are also tested according to USP<85> and USP<161>, and the devices are met the endotoxin acceptance limit of 20 EU/device. The only difference between the subject device and predicate device is the dimension of the cube/block form products. These new product specifications are all within the range of product volume previously cleared for the predicate device, and the lot tests have been done that confirm that the dimension change does not affect the final product and that, as such, it is substantially equivalent to the previously cleared predicate device.

Conclusion

Based on the 510(k) summaries and the information provided herein, it can be concluded that ABCcolla® Bone Matrix is

substantially equivalent to the predicate device, ABCcolla® Bone Graft (K171629).