ACRO Biomedical Co., Ltd.
Dar-Jen Hsieh
Chief Executive Officer
3F, No. 57, Luke 2nd Road,
Lujhu District
Kaohsiung City 82151
TAIWAN

February 1, 2018

Re: K171629
Trade/Device Name: ABCcolla® 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 10, 2018
Received: January 10, 2018

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ACRO Biomedical Co., Ltd.

Indications for Use Statement

510(K) Number (If Known): K171629

Device Name: ABCcolla® Bone Graft

Indications for 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 Graft resorbs and is replaced with 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)

ACRO Biomedical Co., Ltd.

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 K171629 .

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	May 1st, 2017
Name of Device	ABCcolla® Bone Graft
Common Name	Resorbable Bone Void Filler
Classification	Class II
Regulation Number	21 CFR 888.3045
Product Code	MQV
Advisory Panel	ORTHOPEDIC DEVICES
Predicate Device	• ORTHOSS® Resorbable Bone Void Filler, K090401 Ed. Geistlich Soehne Ag Für Chemische Industrie • Bicera™ Resorbable Bone Substitute, K110949 Wiltrom Corporation Limited

Reference Device	• Geistlich Bio-Oss®, K122894 Geistlich Pharma Ag
Device Description	ABCcolla® Bone Graft is a bone mineral matrix of porcine origin. ABCcolla® Bone Graft is physically and chemically comparable to the mineralized matrix of human bone.
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 Graft resorbs and is replaced with bone during the healing process.
Technological Characteristics	ABCcolla® Bone Graft has been designed and manufactured to be substantially equivalent to predicate and reference device through comparison in areas including intended use, material origin, physical structure, chemical characteristics (hydroxyapatite, Ca/P ratio), principles of operation and design (user, how supplied, single use, gamma-irradiation sterilization). ABCcolla® Bone Graft was designed in granule and cube shape similar to the predicate and reference device with different particle size which is between in the maximum and minimum size of the predicate device.
Performance Data	The performance of ABCcolla® Bone Graft, including chemical composition, physical properties, biocompatibility, sterilization, packing, shelf-life, pyrogenicity and pre-clinical animal performance testing were performed to demonstrate substantial equivalence to the predicate devices. Chemical composition (hydroxyapatite, Ca/P ratio) was analyzed via X-ray diffraction (XRD), trace element analysis was performed by inductively coupled plasma/mass spectroscopy (ICP/ MS), particle pore size and morphology was evaluated via scanning

electron microscopy (SEM), porosity was determined by mercury intrusion porosimetry, density was evaluated via tap density analyzer, and moisture content was determined by moisture analyzer.

Biocompatibility studies were performed in accordance with ISO 10993-1, ISO10993-3, ISO10993-4, ISO 10993-5, ISO 10993-6, ISO 10993-10 and ISO10993-11. ABCcolla® Bone Graft was sterilized by gamma-irradiation and the process was validated in accordance with ISO 11137. ABCcolla® Bone Graft also has been tested for its packing integrity. The product shelf-life was evaluated in real-time aging study with passing results. Pyrogenicity was assessed with limulus amebocyte lysate (LAL) method and met the limits of established guidelines.

According to Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device, critical-size bone defect model was performed to evaluated the new bone formation and healing effect of ABCcolla® Bone Graft in pre-clinical animal performance testing.

Substantial Equivalence Summary

ABCcolla® Bone Graft is substantially equivalent to the predicate device with respect to functionality, design, materials, sterilized method, package material, intended use and performance characteristics.

Conclusion

Based on the 510(k) summaries and the information provided herein, we conclude that ABCcolla® Bone Graft is substantially equivalent to the predicate device under the Federal Food, Drug, and Cosmetic Act.