DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 10, 2017

Acro Biomedical Co., Ltd
Dar-Jen Hsieh
CEO
3f., No.57, Luke 2nd Rd, Lujhu Dist.
Kaohsiung City, 82151 TW

Re: K162348
Trade/Device Name: ABCcolla Collagen Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: April 10, 2017
Received: April 10, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162348

Device Name
ABCcolla® Collagen Matrix

Indications for Use *(Describe)*
ABCcolla® Collagen Matrix is intended to be used for management of wounds, including partial and full thickness wounds, venous ulcers, pressure ulcers, chronic vascular ulcers, diabetic ulcers, tunneled/undermined wounds, surgical wounds (donor site/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, and skin tears), first and second-degree burns, draining wounds.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

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 K162348 .

Applicant	ACRO Biomedical Co., Ltd. 3F., 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	July 31, 2016
Name of Device	ABCcolla® Collagen Matrix
Common Name	Wound dressing
Classification	Unclassified
Regulation Number	N/A
Product Code	KGN
Advisory Panel	General & Plastic Surgery
Predicate Device	• CollaWound wound dressing, K090894 Collamatrix Inc.
Reference Device	• Matristem® Wound Matrix, K112409 ACell, Inc.

Device Description	ABCcolla® Collagen Matrix is a decellularized porous porcine collagen material which is biocompatible. ABCcolla® Collagen Matrix absorbs exudates, maintains a moist wound environment, and functions to protect the wound. Pre-wetting makes it supple, conforming to the contour of the wound site. ABCcolla® Collagen Matrix is supplied in double peel-open pouches that is terminally sterilized via gamma irradiation.
Intended Use	ABCcolla® Collagen Matrix is intended to be used for management of wounds, including partial and full thickness wounds, venous ulcers, pressure ulcers, chronic vascular ulcers, diabetic ulcers, tunneled/ undermined wounds, surgical wounds (donor site/ grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, and skin tears), first and second-degree burns, draining wounds.
Sterilization	Gamma irradiation
Packaging	Double peel-open Tyvek pouch
Technological Characteristics	ABCcolla® Collagen Matrix has been designed and manufactured to be substantially equivalent to predicate device and reference device listed for safety and effectiveness. CollaWound wound dressing, K090894 Matristem® Wound Matrix, K112409
Biocompatibility	Biocompatibility studies were performed in accordance with ISO 10993.
Performance Data	Absorbency was performed in accordance with EN 13726-1:2002. *In vitro* degradation, collagen content, and moister content were also analyzed.

Animal Data	Wound healing study in animals was performed to evaluate the wound healing effect of ABCcolla® Collagen Matrix
Substantial Equivalence Summary	ABCcolla® Collagen Matrix is substantially equivalent to the predicate device with respect to functionality, design, materials, sterilized method, absorption, package material, intended use and performance characteristics.
Conclusion	Based on the 510(k) summaries and the information provided herein, we conclude that ABCcolla® Collagen Matrix is substantially equivalent to the predicate device under the Federal Food, Drug, and Cosmetic Act.