October 18, 2024

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

Re: K233378
Trade/Device Name: ABCcolla® Collagen ADM Scaffold
Regulatory Class: Unclassified
Product Code: KGN,
Dated: September 29, 2023
Received: October 2, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Mustafa A. Mazher -S

For Yu-Chieh Chiu, PhD
Assistant Director
DHT4B: Division of Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical and Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233378

Device Name
ABCcolla® Collagen ADM Scaffold

Indications for Use *(Describe)*
ABCcolla® Collagen ADM Scaffold is intended to be used for management of wounds, including 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.

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510(k) Summary

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	Oct.16.2024
Name of Device	ABCcolla® Collagen ADM Scaffold
Common Name	Collagen Wound Dressing
Classification	Unclassified
Regulation Number	N/A
Product Code	KGN
Predicate Device	ABCcolla® Collagen Matrix, K162348

Device Description	ABCcolla® Collagen ADM Scaffold is a decellularized porcine collagen biomaterial from porcine dermis. When applied on a wound, this product helps absorb wound exudates and maintain a moist wound environment.
Intended Use	ABCcolla® Collagen ADM Scaffold is intended to be used for management of wounds, including 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	Packaged in Tyvek pouch and each Tyvek pouch with one glass bottle.
Technological Characteristics	ABCcolla® Collagen ADM Scaffold is a decellularized porcine collagen biomaterial and it is a particle form. When applied on a wound, this product helps absorb wound exudates and maintain a moist wound environment.
Biocompatibility	Biocompatibility Assessments were performed *Cytotoxicity, Intracutaneous Irritation, Skin Sensitization, Acute Systemic Toxicity Test, Pyrogen Test, Subacute Systemic Toxicity Test, Subchronic Systemic Toxicity Test, In vitro Bacterial Gene Mutation Test, In vitro Mouse Lymphoma Test, In vivo Erythrocyte Micronucleus Test, Implantation test (Wound Healing Model) and Toxicological Risk Assessment,* in accordance with ISO 10993.
Performance Data	A study was performed where the ABCcolla® Collagen ADM Scaffold is performed in full thickness skin defect rat model. The results of the study show that device is safe in its application.
Substantial	ABCcolla® Collagen ADM Scaffold is substantially equivalent to

Equivalence Summary	the predicate device with respect to materials, physicochemical properties, biocompatibility and performance characteristics.
Conclusion	Based on the 510(k) summaries and the information provided herein, we conclude that ABCcolla® Collagen ADM Scaffold is substantially equivalent to the predicate device under the Federal Food, Drug, and Cosmetic Act.

Substantial Equivalence Comparison Table

Item	New device	Predicate device	Reference device	Same/ Difference Interpretation
	ABCcolla® Collagen ADM Scaffold	**ABCcolla® Collagen Matrix**	**Cook® ECM Powder**	
1. 510(k) Number	N/A	K162348	K152033	--
2. Product Code	KGN	KGN	KGN	Same
3. Classification	Unclassified	Unclassified	Unclassified	Same
4. Intended Use	ABCcolla® Collagen ADM Scaffold is intended to be used for management of wounds, including venous ulcers, pressure ulcers, chronic vascular ulcers, diabetic ulcers, tunneled/ undermined wounds, surgical wounds (donor site/ grafts, post-Moh's	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,	Indications For Use: Cook® ECM Powder is intended for the management of wounds including: ● partial and full-thickness wounds ● pressure ulcers ● venous ulcers ● diabetic ulcers ● chronic vascular	**ABCcolla® Collagen ADM Scaffold** was same as predicate device and reference device.

Item	New device	Predicate device	Reference device	Same/ Difference Interpretation
	ABCcolla® Collagen ADM Scaffold	**ABCcolla® Collagen Matrix**	**Cook® ECM Powder**	
	surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, and skin tears), first and second-degree burns, draining wounds.	post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, and skin tears), first and second-degree burns, draining wounds.	ulcers ● tunneled/undermined wounds ● surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery podiatric, wound dehiscence) ● trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) ● draining wounds	
5. User	Professional surgical surgeon	Professional surgical surgeon	Professional surgical surgeon	Same
6. Material	Porcine dermis derived collagen material	Porcine small intestinal submucosa derived collagen material	Porcine small intestinal submucosa	The source of material was the same, from porcine tissue.

Item	New device	Predicate device	Reference device	Same/ Difference Interpretation
	ABCcolla® Collagen ADM Scaffold	**ABCcolla® Collagen Matrix**	**Cook® ECM Powder**	
7. Material Characterization	Type I collagen	Type I collagen	Type I collagen	Same
8. Structure	Powder	Sheet form	Powder	**ABCcolla® Collagen ADM Scaffold** was same as reference device. But, different compared to the predicate, the difference does not raise different questions of safety and effectiveness.
9. Dimensions	Particles < 250um	1*2 cm to 5*10 cm 1*1 inch to 2*2 inch	Particles < 1000um	The appearance of new device is similar to reference device; but different compared to the predicate, the difference does not

Item	New device	Predicate device	Reference device	Same/ Difference Interpretation
	ABCcolla® Collagen ADM Scaffold	**ABCcolla® Collagen Matrix**	**Cook® ECM Powder**	
				raise different questions of safety and effectiveness.
10. Packaging	peel packages with glass bottle	Double peel-open Tyvek pouch	n/a	Different compared to the predicate but the difference does not raise different questions of safety and effectiveness.
11. Sterilization Method	Gamma-irradiation	Gamma-irradiation	Ethylene Oxide	The sterilization method of **ABCcolla® Collagen ADM Scaffold** is similar with predicate device.
12. Sterility	SAL $\leq 10^{-6}$ single use	Sterile single use	Sterile single use	Same
13. Biocompatibility	Biocompatibility Assessments were performed *Cytotoxicity,*	Biocompatibility assessment conducted according to ISO 10993-1	Biocompatibility assessment conducted according to ISO 10993-1	**ABCcolla® Collagen ADM Scaffold** is

Item	New device	Predicate device	Reference device	Same/ Difference Interpretation
	ABCcolla® Collagen ADM Scaffold	**ABCcolla® Collagen Matrix**	**Cook® ECM Powder**	
	Intracutaneous Irritation, Skin Sensitization, Acute Systemic Toxicity Test, Pyrogen Test, Subacute Systemic Toxicity Test, Subchronic Systemic Toxicity Test, In vitro Bacterial Gene Mutation Test, In vitro Mouse Lymphoma Test, In vivo Erythrocyte Micronucleus Test, Implantation test (Wound Healing Model) and Toxicological Risk Assessment, in accordance with ISO 10993.			compliance with ISO 10993, and the test results confirmed product safety.