October 13, 2023

SweetBio, Inc
% Carolyn Guthrie
VP of Regulatory
Kapstone Medical
520 Elliot Street
Charlotte, North Carolina 28202

Re: K222143
Trade/Device Name: APIS® Wound Management Device, VERIS™ Wound Management Device
APIS® OTC Wound Management Device, VERIS™ OTC Wound Management Device
Regulatory Class: Unclassified
Product Code: FRO, KGN
Dated: July 19, 2022
Received: July 20, 2022

Dear Carolyn Guthrie:

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.

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control

and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222143

Device Name
APIS® Wound Management Device, VERIS™ Wound Management Device
APIS® OTC Wound Management Device, VERIS™ OTC Wound Management Device

Indications for Use *(Describe)*
Under the supervision of a healthcare professional, APIS® / VERIS™ Wound Management Devices are indicated for use in management of wounds, including:
• Full and partial thickness wounds
• pressure ulcers (stages I -IV)
• venous stasis ulcers
• diabetic ulcers
• abrasion
• surface wounds
• traumatic wounds (healing by secondary intention)
• donor site wounds
• surgical wounds

For over-the-counter use, APIS® OTC / VERIS™ OTC Wound Management Devices may be used for:
• minor abrasions
• lacerations
• minor cuts
• minor scalds and burns

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."

K222143 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone, and Fax Number of Applicant

SweetBio, Inc.
Address: 460 South Highland Street Floor 2, Memphis, TN 38111
Phone: (888)-323-2015

B. Contact Person

Carolyn Guthrie
Regulatory Affairs Consultant
Kapstone Medical, LLC

C. Date Prepared

October 12, 2023

D. Device Name and Classification

Trade Name:	APIS® Wound Management Device VERIS™ Wound Management Device APIS® OTC Wound Management Device VERIS™ OTC Wound Management Device
Common Name:	Dressing, Wound, Drug
Panel:	General and Plastic Surgery
Regulation Number:	Unclassified
Classification:	Unclassified
Product Code:	FRO

E. Predicate Device

APIS® Wound Management Device and VERIS™ Wound Management Device are substantially equivalent to the Rx Only predicate device shown in Table 1. APIS® OTC Wound Management Device and VERIS™ OTC Wound Management Device are substantially equivalent to the OTC predicate device shown in Table 1.

Predicate	510(k) Number	Device	Manufacturer
Primary – Rx Only	K182725	APIS® Wound Management Device	SweetBio, Inc
Primary - OTC	K110546	MediHoney Hydrogel Sheet Dressings with Leptospermum Honey (non-adhesive)	Derma Sciences, Inc

Table 1: Predicate devices

F. Device Description

APIS® Wound Management Device, VERIS™ Wound Management Device, APIS® OTC Wound Management Device and VERIS™ OTC Wound Management Device for the management of wounds, are sterile, single-use devices. APIS® Wound Management Device, VERIS™ Wound Management Device, APIS® OTC Wound Management Device and VERIS™ OTC Wound Management Device are conformable solid sheets that are biodegradable and absorbable. APIS® Wound Management Device, VERIS™ Wound Management Device, APIS® OTC Wound Management Device and VERIS™ OTC Wound Management Device in its final form, is comprised of a highly purified collagen derivative from porcine skin (gelatin), Manuka honey, and hydroxyapatite (HAp).

The intended use of APIS® Wound Management Device, VERIS™ Wound Management Device, APIS® OTC Wound Management Device and VERIS™ OTC Wound Management Device in the management of wounds is to cover and protect the wound, absorb wound exudate, and provide and maintain a moist wound environment. The structural reinforcement of APIS® Wound Management Device, VERIS™ Wound Management Device, APIS® OTC Wound Management Device and VERIS™ OTC Wound Management Device is achieved through the incorporation of hydroxyapatite into the crosslinked collagen derivative structure. The absorption and moisture-retaining properties are based on the manufacturing process and incorporation of honey into the crosslinked structure.

The device is biodegradable and absorbs into the surrounding tissue. The degradation occurs through natural processes such as enzymatic breakdown, hydrolysis and other chemical/biological reactions depending on wound type and level of exudation.

There is no difference between the APIS® Wound Management Device, VERIS™ Wound Management Device, APIS® OTC Wound Management Device and VERIS™ OTC Wound Management Device except APIS® Wound Management Device and APIS® OTC Wound Management Devices have a thickness of 0.03cm and is the compressed form of VERIS™ Wound Management Device and VERIS™ OTC Wound Management Devices which has a thickness of 0.6cm. In other words, VERIS™ Wound Management Devices and VERIS™ OTC Wound Management Devices are 20 times thicker than the APIS® Wound Management Devices and APIS® OTC Wound Management Devices (dressings).

G. Indications for Use

Under the supervision of a healthcare professional, APIS® / VERIS™ Wound Management Devices are indicated for use in management of wounds, including:

- Full and partial thickness wounds
- pressure ulcers (stages I -IV)
- venous stasis ulcers
- diabetic ulcers
- abrasion
- surface wounds
- traumatic wounds (healing by secondary intention)
- donor site wounds
- surgical wounds

For over-the-counter use, APIS® OTC/ VERIS™ OTC Wound Management Devices may be used for:

- minor abrasions
- lacerations
- minor cuts
- minor scalds and burns

H. Technological Comparison – Prescription Use Only

Features	APIS® / VERIS™ Wound Management Device Subject Device	APIS® Wound Management Device Primary Predicate Device	Substantial Equivalence
Indications for Use			
Intended Use	Management of wounds	Management of wounds	Equivalent
Type of Use	Prescription Use	Prescription Use	Equivalent
Indications	• full and partial thickness wounds • pressure ulcers (stages I-IV) • venous stasis ulcers • diabetic ulcers • abrasions • surface wounds • traumatic wounds (healing by secondary intention) • donor sites wounds • surgical wounds	• full and partial thickness wounds • pressure ulcers (stages I-IV) • venous stasis ulcers • diabetic ulcers • abrasions • surface wounds • traumatic wounds (healing by secondary intention) • donor sites wounds • surgical wounds	Equivalent
	• Not for use in infant patients or children under 10kg / 22lbs	• Not for use in infant patients • Not for use on children (2.5cm x 2.5cm, and 5.0cm x 5.0cm)	No new risks of safety or effectiveness
Single Use	Yes	Yes	Equivalent
Sizes	APIS® Wound Management Device: 1.6 x 1.6 cm x 0.03cm 2.5 x 2.5 cm x 0.03cm 5.0 x 5.0 cm x 0.03cm Additional sizes up to 454cm^2	APIS® Wound Management Device: 1.6 x 1.6 cm x 0.03cm 2.5 x 2.5 cm x 0.03cm 5.0 x 5.0 cm x 0.03cm VERIS™: 1.6 x 1.6 cm x 0.6cm 2.5 x 2.5 cm x 0.6cm	Equivalent

Features	APIS® / VERIS™ Wound Management Device Subject Device	APIS® Wound Management Device Primary Predicate Device	Substantial Equivalence
	VERIS Wound Management Device 1.6 x 1.6 cm x 0.6cm 2.5 x 2.5 cm x 0.6cm 5.0 x 5.0 cm x 0.6cm Additional sizes up to 454cm^2	5.0 x 5.0 cm x 0.6cm	
Materials			
Materials of Construction	Manuka Honey	Manuka Honey	Equivalent
	Crosslinked highly purified collagen derivative from porcine skin	Crosslinked highly purified collagen derivative from porcine skin	Equivalent
	Hydroxyapatite	Hydroxyapatite	Equivalent
Technological Characteristics			
Absorbency	A relatively high capacity for absorption of the wound fluid	A relatively high capacity for absorption of the wound fluid	Equivalent
Absorbable	Yes	Yes	Equivalent
Moist environment	Maintains moist wound environment	Maintains moist wound environment	Equivalent
Wound protection	Protects the wound from shear, friction and pressure and is suitable as a protective padding and cushioning device as well as functioning as a dressing.	Protect the wound from shear, friction and pressure, suitable as a protective padding and cushioning device as well as functioning as a dressing.	Equivalent
Performance			
Sterility	Yes, gamma sterilization	Yes, gamma sterilization	Equivalent

I. Technological Comparison – Over-the-Counter

Features	APIS® OTC/ VERIS™ OTC Wound Management Device	MediHoney Hydrogel Sheet Dressings with Leptospermum Honey (non-adhesive)	Substantial Equivalence
	Subject Device	**Primary Predicate Device**	
Indications for Use			
Intended Use	Management of wounds	Management of wounds	Equivalent
Type of Use	Over-the-Counter	Over-the-Counter	Equivalent
Indications	For over-the-counter use, APIS® OTC/ VERIS™ OTC Wound Management Device may be used for: • minor abrasions • lacerations • minor cuts • minor scalds and burns	For over-the-counter use, MediHoney Hydrogel Sheet Dressings with Leptospermum Honey may be used for: • minor abrasions • lacerations • minor cuts • minor scalds and burns	Equivalent
	Not for use in infant patients or children under 10kg / 22lbs	N/A	No new risks of safety or effectiveness per toxicological risk assessment
Single Use	Yes	Yes	Equivalent
Size	APIS® OTC Wound Management Device: 1.6 x 1.6 cm x 0.03cm 2.5 x 2.5 cm x 0.03cm 5.0 x 5.0 cm x 0.03cm Additional sizes up to 454cm^2 VERIS™ OTC Wound Management Device: 1.6 x 1.6 cm x 0.6cm 2.5 x 2.5 cm x 0.6cm 5.0 x 5.0 cm x 0.6cm	6.1 x 6.1 cm 10.98 x 10.98 cm	No new risks of safety or effectiveness per toxicological risk assessment

Features	APIS® OTC/ VERIS™ OTC Wound Management Device	MediHoney Hydrogel Sheet Dressings with Leptospermum Honey (non-adhesive)	Substantial Equivalence
	Subject Device	**Primary Predicate Device**	
	Additional sizes up to 454cm^2		
Structure	Sheet	Sheet	Equivalent
Materials			
Materials of Construction	Manuka Honey	Leptospernum (Manuka) Honey	No increased risk in safety or effectiveness. Both devices are available with Rx Only indications with identical materials of construction
	Crosslinked highly purified collagen derivative from porcine skin	Polymer	
	Hydroxyapatite	N/A	
Technological Characteristics			
Absorbency	A relatively high capacity for absorption of the wound fluid	A relatively high capacity for absorption of the wound fluid	Equivalent
Absorbable	Yes	Yes	Equivalent
Moist environment	Maintains moist wound environment	Maintains moist wound environment	Equivalent
Wound protection	Protects the wound from shear, friction and pressure and is suitable as a protective padding and cushioning device as well as functioning as a dressing.	Protects the wound from shear, friction, and pressure, and is suitable as a protective padding and cushioning device as well as functioning as a dressing.	Equivalent
Performance			
Sterility	Yes, gamma sterilization	Yes, gamma sterilization	Equivalent

J. Performance Data

Nonclinical testing was performed to demonstrate that APIS® / VERIS™ Wound Management Devices and APIS® OTC/ VERIS™ OTC Wound Management Devices are as safe and effective as the legally marketed predicate devices, including fluid uptake, and conformability. Sterilization validation, distribution testing and shelf-life testing have been completed.

Biocompatibility testing and literature demonstrate that APIS® / VERIS™ Wound Management Devices and APIS® OTC/ VERIS™ OTC Wound Management Devices are safe for its intended use. Endotoxin, cytotoxicity, sensitization, irritation, acute systemic toxicity, material-mediated pyrogenicity, subchronic toxicity, genotoxicity, and implantation testing were performed. Chemical characterization and toxicological risk assessment were performed to address the chronic toxicity, and carcinogenicity endpoints.

K. Basis for Substantial Equivalence

APIS® / VERIS™ Wound Management Devices (Rx Only)

The subject and predicate devices for prescription use only are identical with respect to materials, design, intended use, and procedural steps for application. The only difference is a change in the directions of use between the current instructions for use and the proposed instructions for use.

APIS® OTC/ VERIS™ OTC Wound Management Devices (Over-the-Counter)

The subject and predicate devices for over-the-counter use are equivalent with respect to intended use and indications for use. Technological differences do not result in new questions of safety or effectiveness.

L. Conclusion

APIS® / VERIS™ Wound Management Devices (Rx Only)

APIS® / VERIS™ Wound Management Devices are substantially equivalent to the predicate device, Apis Wound Management Device (K182725).

1. Both devices have the same intended use.

2. All the devices have similar technological characteristics in terms of primary constituent, raw material used, sterilization method, geometric specifications, and design of the device. Biocompatibility tests, stability test, and sterilization validation performed on the predicate device are applicable to the current device and hence no new questions on safety and effectiveness are raised.

Hence, a determination of substantial equivalence is supported.

APIS® / VERIS™ Wound Management Devices (Over-the-Counter)

APIS® OTC/ VERIS™ OTC Wound Management Devices are substantially equivalent to the predicate device, MediHoney Hydrogel Sheet Dressings with Leptospermum Honey (K110546).

1. Both devices have the same intended use.

2. Technological differences in materials of construction do not result in new questions of safety or effectiveness.

Hence, a determination of substantial equivalence is supported.