October 17, 2024

Imbed Biosciences
% Albert Rego
Regulatory Consultant
Albert Rego, Ph D, Inc
27001 La Paz Road, Suite 314
Mission Viejo, California 92691

Re: K211943
Trade/Device Name: Microlyte Ag/Lidocaine Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 20, 2024
Received: February 21, 2024

Dear Albert Rego:

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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
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)*
K211943

Device Name
Microlyte® Ag/Lidocaine Wound Dressing

Indications for Use *(Describe)*
Under the supervision of a healthcare professional,
Microlyte® Ag/Lidocaine Wound Dressing may be used for the management of partial and full thickness wounds including diabetic foot ulcers, venous stasis ulcers, pressure ulcers, ischemic ulcers, surgical wounds, post-surgical incisions, donor sites, debrided partial thickness wounds, traumatic wounds, first degree burns, partial thickness burns, abrasions and lacerations.

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.

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510(k) SUMMARY
(As required by 21 CFR 807.92)

SUBMITTER: Imbed Biosciences, Inc.
2241 Pinehurst Drive
Middleton, WI 53562, USA

CONTACT: Ankit Agarwal, PhD
Phone/Fax: 608-237-1525

SUBMISSION DATE: September 23, 2024

DEVICE

TRADE NAME: Microlyte® Ag/Lidocaine Wound Dressing
COMMON NAME: Wound Dressing
CLASSIFICATION NAME: Dressing, Wound With Drug
REGULATORY CLASS: Unclassified
PRODUCT CODE: FRO
CLASSIFICATION PANEL: General and Plastic Surgery
PERFORMANCE STANDARDS: No applicable performance standards have been established under Section 514 of the FD&C Act. Biocompatibility tests were done in conformance with relevant requirements of ISO 10993.

PREDICATE DEVICES:
Primary Predicate – WoundPal® Medicated Wound Dressing (K053476)
Secondary predicate devices –
- Microlyte® Ag Wound Dressing (K153756)
- Amerigel® Wound Dressing (K092086) [Now marketed as ASTERO® Hydrogel + Topical Anesthetic (Lidocaine HCl 4%)]

INTENDED USE:
Microlyte® Ag/Lidocaine Wound Dressing is intended for use as a primary dressing in the local management of wounds. Under the direction of a healthcare professional, Microlyte® Ag/Lidocaine Wound Dressing may be used for the management of wounds such as partial and full thickness diabetic foot ulcers, venous stasis ulcers, pressure ulcers, ischemic ulcers, surgical wounds, post-surgical incisions, donor sites, debrided partial thickness wounds, traumatic wounds, first-degree burns, partial thickness burns, abrasions and lacerations.

DEVICE DESCRIPTION:
Microlyte® Ag/Lidocaine Wound Dressing is a sterile, single use absorbent polymeric matrix composed primarily of synthetic polyvinyl alcohol with 2.5 mg/in^2 of lidocaine hydrochloride USP, with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver, with a maximum of 0.1 mg/in^2 of silver.

MECHANISM OF ACTION: Microlyte® Ag/Lidocaine Wound Dressing absorbs wound fluid and forms a soft matrix that conforms to the wound surface and maintains a moist environment. The matrix contains silver only to prevent or minimize microbial growth within the dressing matrix. The dressing releases Lidocaine Hydrochloride USP for effecting local anesthetic action in painful skin wounds.

INDICATIONS FOR USE:
Under the supervision of a healthcare professional, Microlyte® Ag/Lidocaine Wound Dressing may be used for the management of partial and full thickness wounds including diabetic foot ulcers, venous stasis ulcers, pressure ulcers, ischemic ulcers, surgical wounds, post-surgical incisions, donor sites, debrided partial thickness wounds, traumatic wounds, first degree burns, partial thickness burns, abrasions and lacerations.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:
The form, fit, function and the intended use for the subject device – Microlyte® Ag/Lidocaine Wound Dressing – are substantially equivalent to the cited primary and secondary predicate devices, as summarized in the table below.

Comparison of Technological Characteristics with Predicate Devices

[1]Substantial Equivalence (S.E.)

Category	WoundPal® Medicated Wound Dressing	AMERIGEL® WOUND DRESSING plus (marketed as ASTERO® hydrogel + topical anesthetic Lidocaine HCL 4%)	Microlyte® Ag Wound Dressing	Microlyte® Ag/Lidocaine Wound Dressing	S.E.[1] or not
Manufacturer	AT Squared, LLC	Amerx Health Care Corporation	Imbed Biosciences Inc.	Imbed Biosciences Inc.	N/A
510K Number	K053476	K092086	K153756	K211943	N/A
Class	Unclassified	Unclassified	Unclassified	Unclassified	S.E.
Product code	MGQ	MGQ	FRO	FRO	S.E.
Intended use/ Indications of use	"The product is intended as a primary dressing for use in the local management of painful skin wounds." "Management of partial and full-thickness wounds, including diabetic ulcers, venous stasis ulcers, pressure ulcers, surgical wounds, ischemic ulcers, traumatic wounds, superficial burns, donor sites, and abrasions and lacerations. Absorbs wound exudates and maintains a moist environment."	"Indicated for painful wounds such as stage I-IV pressure ulcers, venous stasis ulcers, ulcerations caused by mixed vascular etiologies, diabetic skin ulcers, first and second degree burns, post-surgical incisions, cuts and abrasions."	"Indicated for the management of wounds and can be used over-the-counter for minor wounds such as abrasions and lacerations, minor cuts, and minor scalds and burns. Under the direction of a healthcare professional, Microlyte® Ag may be used for more serious wounds such as partial and full thickness pressure ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions and lacerations, donor sites and surgical wounds. -May be used over debrided and grafted partial thickness wounds."	"Intended for use as a primary dressing for the local management of wounds. Under the direction of a healthcare professional, Microlyte® Ag/Lidocaine Wound Dressing may be used for the management of wounds such as partial and full thickness diabetic foot ulcers, venous stasis ulcers, pressure ulcers, ischemic ulcers, surgical wounds, post-surgical incisions, donor sites, debrided partial thickness wounds, traumatic wounds, first-degree burns, partial thickness burns, abrasions and lacerations."	S.E.
Description of Device (brief)	"WoundPal is a single use wound dressing consisting of a woven cotton gauze	"Astero® is a hydrated polymer (Hydrogel) wound dressing containing 4%	"Microlyte® Ag Wound Dressing is a sterile, single use unsupported synthetic	"Microlyte® Ag/Lidocaine Wound Dressing is a sterile, single use	S.E.

Category	WoundPal® Medicated Wound Dressing	AMERIGEL® WOUND DRESSING plus (marketed as ASTERO® hydrogel + topical anesthetic Lidocaine HCL 4%)	Microlyte® Ag Wound Dressing	Microlyte® Ag/Lidocaine Wound Dressing	S.E.[1] or not
	treated with an OTC antibiotic mixture composed of Polymyxin B Sulfate USP (10,000 units/gram) and Bacitracin Zinc USP (500 units/gram) in a hydrogel with 2% w/w Lidocaine HCl. Normal saline 0.9% is also added to maintain a moist dressing. A trace amount of oil of wintergreen is added as a fragrance."	w/w Lidocaine HCl USP. Each gram of Astero® contains Lidocaine Hydrochloride USP 4% (40 mg). Lidocaine Hydrochloride USP is chemically designated as acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl). Hydrogel contains polyethylene Glycol (PEG) 400 & polyethylene Glycol 3350 as base, Oak Extract, Meadowsweet Extract, Zinc Acetate, and Water."	absorbent polyvinyl alcohol sheet with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver, with a maximum 0.1 mg/in^2."	absorbent polymeric matrix composed primarily of synthetic polyvinyl alcohol containing 2.5 mg/in^2 lidocaine hydrochloride USP, with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver, with a maximum of 0.1 mg/in^2 of silver."	
Physical composition	"The base woven cotton gauze is treated with an OTC antibiotic mixture composed of Polymyxin B Sulfate USP (10,000 units/gram) and Bacitracin Zinc USP (500 units/gram) in a hydrogel with 2% w/w Lidocaine HCl."	"The base hydrogel is composed of a polyethylene Glycol (PEG) 400 & polyethylene Glycol 3350 as base, Oak Extract, Meadowsweet Extract, Zinc Acetate, and Water."	"The base matrix is composed of a hydrophilic polyvinyl alcohol absorbent sheet, with ionic and metallic silver complexed in a polymeric coating on the surface of the dressing."	The base matrix is composed of a hydrophilic polyvinyl alcohol absorbent sheet with lidocaine hydrochloride USP, and with ionic and metallic silver complexed in a polymeric coating on the surface of the dressing.	S.E.
Antimicrobial form	The base woven cotton gauze is treated with an OTC antibiotic mixture composed of Polymyxin B Sulfate USP and Bacitracin Zinc USP.	N/A	Ionic silver and metallic silver (from silver nitrate)	Ionic silver and metallic silver (from silver nitrate)	S.E.
Antimicrobial content	Polymyxin B Sulfate USP (10,000 units/gram) and Bacitracin Zinc USP (500 units/gram)	N/A, because no antimicrobial agent is present	About 0.1 mg/in^2 of silver	About 0.1 mg/in^2 of silver	S.E.
Lidocaine form and content	Hydrogel contains 2% w/w lidocaine hydrochloride i.e. 20 mg of lidocaine hydrochloride per gram of the hydrogel.	Hydrogel contains 4% w/w lidocaine hydrochloride, i.e. 40 mg of lidocaine hydrochloride per gram of the hydrogel, which is to be applied over 100 cm^2 of wound surface area.	N/A, because no lidocaine is present	The polymeric matrix is impregnated with 2.5 mg/in^2 (= 40 mg/100 cm^2) lidocaine hydrochloride USP. i.e. 40 mg of lidocaine hydrochloride to be applied over 100 cm^2 of wound surface area.	S.E.
Mechanism of action	"The product is intended as a primary dressing for use in the local management of painful skin wounds. The antibiotic mixture is present to help prevent bacterial contamination of the	"By providing moisture to the wound, Astero® create a moist healing environment, which promotes granulation, epithelialization, and autolytic debridement. The high water content of	"The dressing absorbs wound fluid and forms a soft gel that conforms to the wound surface and maintains a moist environment. The dressing contains silver only to prevent or minimize	The dressing absorbs wound fluid and forms a soft matrix that conforms to the wound surface and maintains a moist environment. The matrix contains silver only to prevent or minimize	S.E.

Category	WoundPal® Medicated Wound Dressing	AMERIGEL® WOUND DRESSING plus (marketed as ASTERO® hydrogel + topical anesthetic Lidocaine HCL 4%)	Microlyte® Ag Wound Dressing	Microlyte® Ag/Lidocaine Wound Dressing	S.E.[1] or not
	dressing. The dressing may be held in place with a variety of secondary dressings, including an additional bandage or with the addition of an outer layer comprised of a polymeric film that may be secured by applying zinc oxide ointment USP between the film and intact skin surrounding the wound."	hydrogel dressings cools the wound, producing pain relief that can last up to 6 hours. Dressing-change discomfort is also reduced because Astero® doesn't adhere to the wound surface. Astero® releases Lidocaine Hydrochloride USP from the Neutral (pH 7-7.2) hydrogel to stabilize the neuronal membrane by inhibiting the ionic fluxes required for initiation and conduction of impulses, thereby effecting local anesthetic action."	microbial growth within the dressing."	microbial growth within the matrix. The dressing releases Lidocaine Hydrochloride USP for effecting local anesthetic action in painful skin wounds.	
Bio-compatibility	"Because of the long history of safe use of the components of WoundPal® Medicated Wound Dressing independently, and in combination, the device does not raise any new safety issues and biocompatibility testing was not performed."	"Lidocaine HCl is well known to be GRASE (generally regarded as safe and effective)." Biocompatibility of the base hydrogel "was previously established by in-vitro cytotoxicity test, dermal sensitization test in rabbits and sensitization test on guinea pigs."	Cytotoxicity, Sensitization, Acute intracutaneous reactivity, Acute systemic toxicity, Tissue implantation, and Sub-acute/Sub-chronic toxicity. All tests performed in accordance with the applicable ISO-10993 standards.	Cytotoxicity, Sensitization, Acute intracutaneous reactivity, Acute systemic toxicity, Tissue implantation, Sub-acute/Sub-chronic toxicity, Porcine wound healing, Material mediated pyrogenicity. All tests performed at in accordance with of the applicable ISO-10993 standards.	S.E.
Antimicrobial Activity within the dressing	Yes.	No	Yes. >4 $\log_{10}$ reduction in viable counts of test microbes	Yes. >4 $\log_{10}$ reduction in viable counts of test microbes	S.E.
Sterility	Sterile	Not sterile	Sterile	Sterile	S.E.
Packaging	Supplied as sterile sheets of 4"x4" size.	Supplied as 30 mL Airless Metered Dose Bottle. Each pump of the Astero® bottle will deliver 0.25 mL of Astero® (10 mg Lidocaine Hydrochloride USP), enough to cover a 2 inch by 2 inch area of skin.	Supplied as sterile sheets of 1"x1", 2"x2", 2"x9", 4"x4", 4"x9", 6"x6", 8"x8" and 8"x10" sizes. Packaged in single use heat sealed medical grade foil pouches.	Supplied as sterile sheets of 1"x1", 2"x2", 2"x9", 4"x4", 4"x9", and 6"x6" sizes. Packaged in single use heat sealed medical grade foil pouches.	S.E.

Microlyte® Ag/Lidocaine Wound Dressing is *substantially equivalent* in the form, fit, function, and intended use to the cited primary predicate device – WoundPal® Medicated Wound Dressing (K053476). Both the dressings have the same technological characteristics including film dressing, sterile, single use,

and absorbent. Both the dressings contain antimicrobial agent(s) and a local anesthetic. They both have the same design properties and product specifications such as shape, size, and geometry.

Both the subject and the primary predicate device function as a primary wound dressing, where absorbent sheet of the dressings absorbs wound exudate and maintains a moist wound environment to support the normal wound healing. They both contain antimicrobial agents in the dressing to minimize microbial growth within the dressings and lidocaine HCl in the dressing for the local pain management in wounds.

The stated differences in the technological characteristics of Microlyte® Ag/Lidocaine Wound Dressing and its predicates are minor and do not present any new questions regarding its safety and performance, as documented by biocompatibility and performance testing.

PERFORMANCE AND SAFETY DATA:
No applicable performance standards have been established under Section 514 of the FD&C Act. The following performance data were provided in support of the substantial equivalence determination. All tests were performed on final finished packaged sterilized product. All testing was done in compliance to the current FDA recognized editions of USP and ASTM standards.

PHYSICAL PERFORMANCE: The technological characteristics of the device such as appearance, size, thickness, color, silver loading, lidocaine loading, water uptake capacity, tensile strength, and oxygen and water vapor transmission rates were evaluated and determined to pass the performance acceptance criteria. The device released about 2.5 mg/in^2 (= 40 mg/100 cm^2) Lidocaine Hydrochloride USP in a simulated wound fluid within an hour. The device released a total of about 0.1 mg/in^2 of silver over 3 days in a simulated wound fluid.

ANTIMICROBIAL PERFORMANCE: Sustained antimicrobial activity for up to 3 days was demonstrated by relevant standard *in vitro* microbiological assays in a simulated wound fluid using an ISO standardized test method. The dressing caused within 24 hours more than 4 $\log_{10}$ reduction in the viable counts of a broad spectrum of test organisms (cells/cm^2) incubated on its surface, including, *Staphylococcus aureus* (ATCC 6538), MRSA (ATCC 33591), VRE (ATCC 55175), *Pseudomonas aeruginosa* (ATCC 15692), *Escherichia coli* (ATCC 8739), *Klebsiella pneumoniae (ATCC 4352), Candida tropicalis (ATCC 750)* and *Candida albicans* (ATCC 10231). The results verify that the antimicrobial silver in the dressing suppresses the growth of microorganisms on the dressing and is effective in preventing microbial colonization of the dressing.

BIOCOMPATIBILITY: The biocompatibility of Microlyte® Ag/Lidocaine Wound Dressing has been demonstrated through appropriate *in vitro* and *in vivo* tests, including cytotoxicity, acute systemic toxicity, acute intracutaneous reactivity, skin sensitization, sub-acute/sub-chronic systemic toxicity, tissue implantation, and material mediated pyrogenicity tests. All tests were performed in compliance with GLP regulations in accordance with ISO-10993-1, Biological Evaluations of Medical Devices Part 1: Evaluation and Testing. The test results indicated that Microlyte® Ag/Lidocaine wound dressing has passed toxicity and safety tests and is safe for intended use similar to predicate devices.

ANIMAL STUDY: A porcine wound healing study in full-thickness wounds was performed based in part on ISO 10993-6: tests for local effects after implantation. The results of the study concluded that the subject device demonstrated minimal to no local reaction compared to cited predicate devices following repeated dermal applications over 10 and 24 days and supported the normal wound healing progression. There were no macroscopic or microscopic differences detected in the wound healing progression with the test article and controls.

PYROGENICITY TESTING: A USP Kinetic-Turbidity LAL assay test-specification has been validated as an end-product release test for the presence of endotoxin. The test articles met the current FDA and USP requirements for limit of endotoxin detected on medical devices. Microlyte® Ag/Lidocaine Wound Dressing was determined to be non-pyrogenic.

CLINICAL STUDY: Clinical data is not needed to support substantial equivalence to previously cleared predicate devices.

DICUSSSION

Based on the similarities in the device design, material composition, function, mechanism of action, biocompatibility, performance, and the proposed intended use and indications, it is determined that Microlyte® Ag/Lidocaine Wound Dressing is *substantially equivalent* to the cited primary predicate device. The differences in the technological characteristics between the subject and predicate devices are minor and do not raise any new questions regarding its safety and intended use.

CONCLUSIONS

Microlyte® Ag/Lidocaine Wound Dressing is substantially equivalent in function and intended use to the previously cleared predicate devices.