



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

August 4, 2016

Imbed Biosciences, Inc.  
c/o Albert Rego, Ph.D.  
27001 La Paz Road, Suite 314  
Mission Viejo, CA 92691

Re: K153756

Trade/Device Name: Microlyte Ag  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: June 30, 2016  
Received: July 6, 2016

Dear Dr. 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 (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" (21CFR 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 yours,

**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

## Indications for Use

510(k) Number (if known)

K153756

Device Name

Microlyte™ Ag

Indications for Use (Describe)

Under the supervision of a healthcare professional,

Microlyte™ Ag wound dressing may be used for the management of:

-Wounds,

-Partial and full thickness wounds including 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.

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  
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[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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."*

## Indications for Use

510(k) Number (if known)

K153756

Device Name

Microlyte™ Ag

Indications for Use (Describe)

For over-the-counter use,

Microlyte™ Ag wound dressing may be used for: abrasions, lacerations, minor cuts, and 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.

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Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
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[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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**

(As required by 21 CFR 807.92)

Rx Only

**I. SUBMITTER:** Imbed Biosciences, Inc.  
5520 Nobel Drive, Suite 100  
Madison, WI 53711, USA

**CONTACT:** Ankit Agarwal, PhD  
CEO  
Phone: 515.708.1330  
Fax: 608.237.1271  
Email: [ankit@imbedbio.com](mailto:ankit@imbedbio.com)

**SUBMISSION DATE:** December 2015

**II. DEVICE**

**TRADE NAME:** Microlyte™ Ag  
**COMMON NAME:** microfilm wound dressing  
**CLASSIFICATION NAME:** Dressing, Wound, 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.

**III. PREDICATE DEVICES:** AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing; K080383  
AcryDerm® (or SilvaSorb®) Silver Antimicrobial Dressing; K002599  
Silverlon™ Contact Wound Dressing; K981299

**IV. INTENDED USE:**

Microlyte™ Ag wound dressing is 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. Microlyte™ Ag wound dressing may be used over debrided and grafted partial thickness wounds.

**V. DEVICE DESCRIPTION:**

Microlyte™ Ag wound dressing is a sterile, single use unsupported synthetic absorbent polyvinyl alcohol hydrogel sheet with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver, with a maximum of 0.4 mg of silver in a 2 inch x 2 inch dressing, equivalent to 0.1 mg/sq. inch.

**MECHANISM OF ACTION:** 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 microbial growth within the dressing.

#### **VI. INDICATIONS FOR USE:**

*Under the supervision of a healthcare professional*, Microlyte™ Ag wound dressing may be used for the management of:

- Wounds ,
- Partial and full thickness wounds including 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.

#### **VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:**

The predicate devices used for direct comparison and the determination of substantial equivalence in function and intended use are:

- AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing (K080383)
- AcryDerm® (or Silvasorb® - Current Trade Name) Silver Antimicrobial Wound Dressing (K002599)
- Silverlon™ Contact Wound Dressing (K981299)

The technological characteristics of Microlyte™ Ag wound dressing such as sterile, single use, flexible primary contact wound dressing, permeability to oxygen and moisture, absorption of wound exudate, and protection against microbial contamination of the dressing, are substantially equivalent to the predicate devices cited. Microlyte™ Ag and the predicate devices have same intended use and are recommended for same indications for use.

Microlyte™ Ag and the predicate devices are of similar composition consisting of an absorbent matrix to absorb wound exudate and create a moist wound environment supportive of the healing process. Microlyte™ Ag contains silver in the absorbent matrix, similar to predicate devices, which may control microbial contamination of the dressing. A comparison of the technological characteristics of Microlyte™ Ag wound dressing and cited predicate devices are summarized in the table below.

Microlyte™ Ag is substantially equivalent to *Aquacel Ag Antimicrobial Dressing* in that an aqueous base hydrogel matrix absorbs wound fluid and forms a soft gel that conforms to the wound surface and maintains a moist environment. They both contain ionic silver from silver nitrate. Primary difference is in the polymeric composition of the base matrix and metallic silver. *Aquacel Ag* is composed of a natural polymer- sodium carboxymethylcellulose, whereas Microlyte™ Ag is composed of a non-toxic synthetic polymer- polyvinyl alcohol. However, this minor difference doesn't affect their function, safety and effectiveness.

Microlyte™ Ag is substantially equivalent to *Acryderm Silver Antimicrobial Wound Dressing* in that a synthetic absorbent hydrogel sheet containing silver manages wound moisture. Microlyte™ Ag is substantially equivalent to *Silverlon Contact Wound Dressing* in that an absorbent matrix contacts the wound and where metallic silver is present in both products to prevent or minimize microbial growth within the dressing.

The stated differences in technological characteristics of Microlyte™ Ag and its predicates are minor and do not present any new questions regarding its safety and effectiveness, as documented by biocompatibility and performance testing.

### Comparison of Technological Characteristics with Predicate Devices

<sup>1</sup>Substantial Equivalence (S.E.)

CATEGORY	AQUACEL® AG WITH HYDROFIBER® SILVER IMPREGNATED ANTIMICROBIAL DRESSING	ACRYDERM® (or SILVASORB®) SILVER ANTIMICROBIAL WOUND DRESSING	SILVERLON™ CONTACT WOUND DRESSING	MICROLYTE™ AG WOUND DRESSING	S.E. <sup>1</sup> or not
<b>Manufacturer</b>	ConvaTec Limited	AcryMed Inc.	Argentum Medical LLC	Imbed Biosciences Inc.	N/A
<b>510K Number</b>	K080383	K002599	K981299	Subject of this 510(K)	N/A
<b>Class</b>	Unclassified	Unclassified	Unclassified	Unclassified	S.E.
<b>Product code</b>	FRO	FRO	FRO	FRO	S.E.
<b>Intended use/ Indications for use</b>	Under the direction of a healthcare professional, Aquacel Ag may be used for more serious wounds such as diabetic foot and leg ulcers, pressure ulcers (partial and full-thickness), surgical wounds or traumatic wounds left to heal by secondary intent, and partial thickness burns (second degree), wounds that are prone to bleeding, oncology wounds and management of painful wounds.”	“Intended for use on partial and full thickness external wounds such as pressure sores, arterial ulcers, diabetic ulcers, and venous stasis ulcers and on acute wounds such as draining surgical wounds, lacerations, donor site, and exudating first and second degree burns, and abrasions.” “May be used over debrided and grafted partial thickness wounds.”	“Silverlon contact wound dressings are external wound dressings that are designed as an interface between the wound and a conventional occlusive dressing. Silver contact wound dressings are sterile, non-adherent dressings intended for local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure, and diabetic).”	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.	S.E.
<b>Description of Device (brief)</b>	“Soft, sterile, non-woven pad or ribbon dressing composed of absorbent hydrocolloid fibers (sodium carboxymethylcellulose) and 1.2% ionic silver which allows for a maximum of 12 mg of silver for a 4 inch x 4 inch dressing.”	“Sterile, single use unsupported synthetic absorbent polyacrylate hydrogel containing silver halide and stabilizers. The product carries the general classification name- Hydrophilic wound dressing.”	“Silverlon contact wound dressings are made of flexible, sterile, non-adherent fabric consisting of 1 or 4 layers of a knitted continuous nylon fiber substrate with a metallic silver surface containing approximately 1% silver oxide.”	Sterile, single use unsupported synthetic absorbent polyvinyl alcohol hydrogel sheet with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver, with a maximum of 0.4 mg of silver in a 2 inch x 2 inch dressing, equivalent to 0.1 mg/sq. inch.	S.E.
<b>Physical composition</b>	Sodium carboxymethylcellulose fibers and 1.2% ionic silver.	“The base matrix is composed of a hydrophilic polyacrylate absorbent sheet containing silver halide and stabilizers.”	“The surface of nylon fibers in Silverlon contact wound dressing consists of a thin layer of metallic silver containing approximately 1% silver oxide.”	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.	S.E.
<b>Silver form</b>	Ionic silver (from silver nitrate) complexed inside a sodium carboxymethylcellulose matrix	Silver chloride complex inside an aqueous base polyacrylate hydrogel matrix.	Surface coating of a thin layer of metallic silver containing ~1% silver oxide is deposited on the nylon fibers by a proprietary autocatalytic electroless	Hydrogel sheet has a polymeric surface coating that contains ionic silver (from silver nitrate) and metallic silver.	S.E.

CATEGORY	AQUACEL® AG WITH HYDROFIBER® SILVER IMPREGNATED ANTIMICROBIAL DRESSING	ACRYDERM® (or SILVASORB®) SILVER ANTIMICROBIAL WOUND DRESSING	SILVERLON™ CONTACT WOUND DRESSING	MICROLYTE™ AG WOUND DRESSING	S.E. <sup>1</sup> or not
			chemical plating technique.		
<b>Silver content</b>	About 12 mg/100 cm <sup>2</sup>	Nominally 0.13% by weight of silver chloride	About 546 mg/100 cm <sup>2</sup>	About 1.6 mg/100 cm <sup>2</sup>	S.E.
<b>Mechanism of action</b>	"The dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). The moist wound healing environment and control of wound bacteria supports the body's healing process and helps reduce the risk of wound infection. The silver in the dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound."	"Moist sheet wound dressing that contains silver halide that may help to reduce growth of microbial contaminants of the dressing."	"Silverlon contact wound dressings are designed to intimately contact the wound as a primary dressing and permit the passage of fluids. The silver provides effective protection of the dressing against microbial contamination."  "The nylon fabric permits the passage of oxygen and fluids to and from the dressing." Silver coating delivers antimicrobial silver ions in the dressing when activated by moisture.	The dressing absorbs wound fluid and forms a soft gel that intimately conforms to the wound surface and maintains a moist environment.  The dressing contains silver only to prevent or minimize microbial growth within the dressing.	S.E.
<b>Bio-compatibility</b>	Assessed according to Part 1 of ISO-10993 standards	Assessed according to Part 1 of ISO-10993 standards	Cytotoxicity, Sensitization, Acute intracutaneous reactivity, Acute systemic toxicity, Tissue compatibility.  All tests performed at NAMSA (Northwood, OH) in accordance with Part 1 of ISO-10993 standards.	Cytotoxicity, Sensitization, Acute intracutaneous reactivity, Acute systemic toxicity, Tissue implantation, and Sub-acute/Sub-chronic toxicity.  All tests performed at NAMSA (Northwood, OH) in accordance with Part 1 of ISO-10993 standards.	S.E.
<b>Antimicrobial</b>	Yes	Yes	Yes	Yes. 4 log <sub>10</sub> reduction in viable counts of test microbes	S.E.
<b>Sterility</b>	Gamma irradiation	Gamma irradiation	Gamma irradiation	Electron-beam irradiation	S.E.
<b>Packaging</b>	2"x2", 4"x4", 6"x6", 8"x12" sizes in individually sealed pouches	Supplied as sterile sheets of 2"x2", 2"x4", 4"x4", 4"x8", 8"x8" sizes in single use heat sealed foil pouches	4"x4", 4"x8", 4"x12" sizes in individually sealed envelopes	Supplied as sterile sheets of 1"x1", 2"x2", 4"x4", 6"x6", 8"x8" and 8"x10" sizes in single use heat sealed foil pouches	S.E.

## VIII. PERFORMANCE DATA

No applicable performance standards have been established under Section 514 of the FD&C Act. The following FDA guidance document was referred for performance testing:

-*Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Wound Dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC) Additive*. Document issued on: October 16, 2009.

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, water uptake capacity, tensile strength, and oxygen and water vapor transmission rates were evaluated and determined to pass the performance acceptance criteria.

**ANTIMICROBIAL PERFORMANCE:** Antimicrobial activity has been demonstrated by relevant standard *in vitro* microbiological assays using a GMP protocol. The dressing caused within 24 hours more than 4 log<sub>10</sub> reduction in the viable counts of a broad spectrum of test organisms (cells/cm<sup>2</sup>) incubated on its surface, including, *Staphylococcus aureus* (ATCC 6538), MRSA (ATCC 33591), VRE (ATCC 55175), *Pseudomonas aeruginosa* (ATCC 9027), *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 wound dressing has been demonstrated through appropriate *in vitro* and *in vivo* tests, including cytotoxicity, acute systemic toxicity, acute intracutaneous reactivity, skin sensitization, subacute/subchronic systemic toxicity, and tissue implantation 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 results indicated that Microlyte™ Ag wound dressing has passed toxicity and safety tests and is safe for intended use similar to predicate devices.

**PYROGENICITY TESTING:** A USP Kinetic-Chromogenic 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 wound dressings were determined to be non-pyrogenic.

**CLINICAL STUDY:** Clinical data was not provided and was not needed to support substantial equivalence to previously cleared predicate devices.

## IX. DISCUSSION

The intended use, indications for use, device design, function, mechanism of action, material composition, biocompatibility, and performance of Microlyte™ Ag wound dressings, as designed and manufactured, are determined by Imbed Biosciences Inc. to be substantially equivalent to predicate devices cited within this submission. The differences in technological characteristics between the Microlyte™ Ag and the predicate devices are minor and do not present any new questions regarding its safety and effectiveness for the intended use.

**X. CONCLUSIONS**

Microlyte™ Ag wound dressing is substantial equivalent in function and intended use to previously cleared predicate devices.

**510(k) SUMMARY**

(As required by 21 CFR 807.92)  
Over-the-counter (OTC)

- I. SUBMITTER:** Imbed Biosciences, Inc.  
5520 Nobel Drive, Suite 100  
Madison, WI 53711, USA
- CONTACT:** Ankit Agarwal, PhD  
CEO  
Phone: 515.708.1330  
Fax: 608.237.1271  
Email: [ankit@imbedbio.com](mailto:ankit@imbedbio.com)
- SUBMISSION DATE:** December 2015
- II. DEVICE**
- TRADE NAME:** Microlyte™ Ag  
**COMMON NAME:** microfilm wound dressing  
**CLASSIFICATION NAME:** Dressing, Wound, 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.
- III. PREDICATE DEVICES:** AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing; K080383  
AcryDerm® (or SilvaSorb®) Silver Antimicrobial Dressing; K002599  
Silverlon™ Contact Wound Dressing; K981299

**IV. INTENDED USE:**

Microlyte™ Ag wound dressing is 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. Microlyte™ Ag wound dressing may be used over debrided and grafted partial thickness wounds.

**V. DEVICE DESCRIPTION:**

Microlyte™ Ag wound dressing is a sterile, single use unsupported synthetic absorbent polyvinyl alcohol hydrogel sheet with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver, with a maximum of 0.4 mg of silver in a 2 inch x 2 inch dressing, equivalent to 0.1 mg/sq. inch.

**MECHANISM OF ACTION:** 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 microbial growth within the dressing.

#### **VI. INDICATIONS FOR USE:**

*For over-the-counter use,* Microlyte™ Ag wound dressing may be used for: abrasions, lacerations, minor cuts, and minor scalds and burns.

#### **VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:**

The predicate devices used for direct comparison and the determination of substantial equivalence in function and intended use are:

- AQUACEL® Ag with Hydrofiber® Silver Impregnated Antimicrobial Dressing (K080383)
- AcryDerm® (or Silvasorb® - Current Trade Name) Silver Antimicrobial Wound Dressing (K002599)
- Silverlon™ Contact Wound Dressing (K981299)

The technological characteristics of Microlyte™ Ag wound dressing such as sterile, single use, flexible primary contact wound dressing, permeability to oxygen and moisture, absorption of wound exudate, and protection against microbial contamination of the dressing, are substantially equivalent to the predicate devices cited. Microlyte™ Ag and the predicate devices have same intended use and are recommended for same indications for use.

Microlyte™ Ag and the predicate devices are of similar composition consisting of an absorbent matrix to absorb wound exudate and create a moist wound environment supportive of the healing process. Microlyte™ Ag contains silver in the absorbent matrix, similar to predicate devices, which may control microbial contamination of the dressing. A comparison of the technological characteristics of Microlyte™ Ag wound dressing and cited predicate devices are summarized in the table below.

Microlyte™ Ag is substantially equivalent to *Aquacel Ag Antimicrobial Dressing* in that an aqueous base hydrogel matrix absorbs wound fluid and forms a soft gel that conforms to the wound surface and maintains a moist environment. They both contain ionic silver from silver nitrate. Primary difference is in the polymeric composition of the base matrix and metallic silver. *Aquacel Ag* is composed of a natural polymer- sodium carboxymethylcellulose, whereas Microlyte™ Ag is composed of a non-toxic synthetic polymer- polyvinyl alcohol. However, this minor difference doesn't affect their function, safety and effectiveness.

Microlyte™ Ag is substantially equivalent to *Acryderm Silver Antimicrobial Wound Dressing* in that a synthetic absorbent hydrogel sheet containing silver manages wound moisture. Microlyte™ Ag is substantially equivalent to *Silverlon Contact Wound Dressing* in that an absorbent matrix contacts the wound and where metallic silver is present in both products to prevent or minimize microbial growth within the dressing.

The stated differences in technological characteristics of Microlyte™ Ag and its predicates are minor and do not present any new questions regarding its safety and effectiveness, as documented by biocompatibility and performance testing.

**Comparison of Technological Characteristics with Predicate Devices**

<sup>1</sup>Substantial Equivalence (S.E.)

CATEGORY	AQUACEL® AG WITH HYDROFIBER® SILVER IMPREGNATED ANTIMICROBIAL DRESSING	ACRYDERM® (or SILVASORB®) SILVER ANTIMICROBIAL WOUND DRESSING	SILVERLON™ CONTACT WOUND DRESSING	MICROLYTE™ AG WOUND DRESSING	S.E. <sup>1</sup> or not
<b>Manufacturer</b>	ConvaTec Limited	AcryMed Inc.	Argentum Medical LLC	Imbed Biosciences Inc.	N/A
<b>510K Number</b>	K080383	K002599	K981299	Subject of this 510(K)	N/A
<b>Class</b>	Unclassified	Unclassified	Unclassified	Unclassified	S.E.
<b>Product code</b>	FRO	FRO	FRO	FRO	S.E.
<b>Intended use/ Indications for use</b>	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.	“Intended for use on partial and full thickness external wounds such as pressure sores, arterial ulcers, diabetic ulcers, and venous stasis ulcers and on acute wounds such as draining surgical wounds, lacerations, donor site, and exudating first and second degree burns, and abrasions.” “May be used over debrided and grafted partial thickness wounds.”	“Silverlon contact wound dressings are external wound dressings that are designed as an interface between the wound and a conventional occlusive dressing. Silver contact wound dressings are sterile, non-adherent dressings intended for local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure, and diabetic).”	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.	S.E.
<b>Description of Device (brief)</b>	“Soft, sterile, non-woven pad or ribbon dressing composed of absorbent hydrocolloid fibers (sodium carboxymethylcellulose) and 1.2% ionic silver which allows for a maximum of 12 mg of silver for a 4 inch x 4 inch dressing.”	“Sterile, single use unsupported synthetic absorbent polyacrylate hydrogel containing silver halide and stabilizers. The product carries the general classification name- Hydrophilic wound dressing.”	“Silverlon contact wound dressings are made of flexible, sterile, non-adherent fabric consisting of 1 or 4 layers of a knitted continuous nylon fiber substrate with a metallic silver surface containing approximately 1% silver oxide.”	Sterile, single use unsupported synthetic absorbent polyvinyl alcohol hydrogel sheet with a polymeric surface coating containing ionic and metallic silver. It has very low amounts of silver, with a maximum of 0.4 mg of silver in a 2 inch x 2 inch dressing, equivalent to 0.1 mg/sq. inch.	S.E.
<b>Physical composition</b>	Sodium carboxymethylcellulose fibers and 1.2% ionic silver.	“The base matrix is composed of a hydrophilic polyacrylate absorbent sheet containing silver halide and stabilizers.”	“The surface of nylon fibers in Silverlon contact wound dressing consists of a thin layer of metallic silver containing approximately 1% silver oxide.”	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.	S.E.
<b>Silver form</b>	Ionic silver (from silver nitrate) complexed inside a sodium carboxymethylcellulose matrix	Silver chloride complex inside an aqueous base polyacrylate hydrogel matrix.	Surface coating of a thin layer of metallic silver containing ~1% silver oxide is deposited on the nylon fibers by a proprietary autocatalytic electroless	Hydrogel sheet has a polymeric surface coating that contains ionic silver (from silver nitrate) and metallic silver.	S.E.

CATEGORY	AQUACEL® AG WITH HYDROFIBER® SILVER IMPREGNATED ANTIMICROBIAL DRESSING	ACRYDERM® (or SILVASORB®) SILVER ANTIMICROBIAL WOUND DRESSING	SILVERLON™ CONTACT WOUND DRESSING	MICROLYTE™ AG WOUND DRESSING	S.E. <sup>1</sup> or not
			chemical plating technique.		
<b>Silver content</b>	About 12 mg/100 cm <sup>2</sup>	Nominally 0.13% by weight of silver chloride	About 546 mg/100 cm <sup>2</sup>	About 1.6 mg/100 cm <sup>2</sup>	S.E.
<b>Mechanism of action</b>	"The dressing absorbs high amounts of wound fluid and bacteria and creates a soft, cohesive gel that intimately conforms to the wound surface, maintains a moist environment and aids in the removal of non-viable tissue from the wound (autolytic debridement). The moist wound healing environment and control of wound bacteria supports the body's healing process and helps reduce the risk of wound infection. The silver in the dressing kills wound bacteria held in the dressing and provides an antimicrobial barrier to protect the wound."	"Moist sheet wound dressing that contains silver halide that may help to reduce growth of microbial contaminants of the dressing."	"Silverlon contact wound dressings are designed to intimately contact the wound as a primary dressing and permit the passage of fluids. The silver provides effective protection of the dressing against microbial contamination."  "The nylon fabric permits the passage of oxygen and fluids to and from the dressing." Silver coating delivers antimicrobial silver ions in the dressing when activated by moisture.	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 microbial growth within the dressing.	S.E.
<b>Bio-compatibility</b>	Assessed according to Part 1 of ISO-10993 standards	Assessed according to Part 1 of ISO-10993 standards	Cytotoxicity, Sensitization, Acute intracutaneous reactivity, Acute systemic toxicity, Tissue compatibility.  All tests performed at NAMSA (Northwood, OH) in accordance with Part 1 of ISO-10993 standards.	Cytotoxicity, Sensitization, Acute intracutaneous reactivity, Acute systemic toxicity, Tissue implantation, and Sub-acute/Sub-chronic toxicity.  All tests performed at NAMSA (Northwood, OH) in accordance with Part 1 of ISO-10993 standards.	S.E.
<b>Antimicrobial</b>	Yes	Yes	Yes	Yes. 4 log <sub>10</sub> reduction in viable counts of test microbes	S.E.
<b>Sterility</b>	Gamma irradiation	Gamma irradiation	Gamma irradiation	Electron-beam irradiation	S.E.
<b>Packaging</b>	2"x2", 4"x4", 6"x6", 8"x12" sizes in individually sealed pouches	Supplied as sterile sheets of 2"x2", 2"x4", 4"x4", 4"x8", 8"x8" sizes in single use heat sealed foil pouches	4"x4", 4"x8", 4"x12" sizes in individually sealed envelopes	Supplied as sterile sheets of 1"x1", 2"x2", 4"x4", 6"x6", 8"x8" and 8"x10" sizes in single use heat sealed foil pouches	S.E.

### VIII. PERFORMANCE DATA

No applicable performance standards have been established under Section 514 of the FD&C Act. The following FDA guidance document was referred for performance testing:

-*Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Wound Dressing with Poly(diallyl dimethyl ammonium chloride) (pDADMAC) Additive*. Document issued on: October 16, 2009.

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, water uptake capacity, tensile strength, and oxygen and water vapor transmission rates were evaluated and determined to pass the performance acceptance criteria.

**ANTIMICROBIAL PERFORMANCE:** Antimicrobial activity has been demonstrated by relevant standard *in vitro* microbiological assays using a GMP protocol. The dressing caused within 24 hours more than 4 log<sub>10</sub> reduction in the viable counts of a broad spectrum of test organisms (cells/cm<sup>2</sup>) incubated on its surface, including, *Staphylococcus aureus* (ATCC 6538), MRSA (ATCC 33591), VRE (ATCC 55175), *Pseudomonas aeruginosa* (ATCC 9027), *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 wound dressing has been demonstrated through appropriate *in vitro* and *in vivo* tests, including cytotoxicity, acute systemic toxicity, acute intracutaneous reactivity, skin sensitization, subacute/subchronic systemic toxicity, and tissue implantation 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 results indicated that Microlyte™ Ag wound dressing has passed toxicity and safety tests and is safe for intended use similar to predicate devices.

**PYROGENICITY TESTING:** A USP Kinetic-Chromogenic 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 wound dressings were determined to be non-pyrogenic.

**CLINICAL STUDY:** Clinical data was not provided and was not needed to support substantial equivalence to previously cleared predicate devices.

### IX. DISCUSSION

The intended use, indications for use, device design, function, mechanism of action, material composition, biocompatibility, and performance of Microlyte™ Ag wound dressings, as designed and manufactured, are determined by Imbed Biosciences Inc. to be substantially equivalent to predicate devices cited within this submission. The differences in technological characteristics between the Microlyte™ Ag and the predicate devices are minor and do not present any new questions regarding its safety and effectiveness for the intended use.

**X. CONCLUSIONS**

Microlyte™ Ag wound dressing is substantially equivalent in function and intended use to previously cleared predicate devices.