November 23, 2018

MedCu Technologies, Ltd.
% Tali Hazan
RA Consultant
Talmed Ltd.
MP Upper Galilee
Ramot Naftali, 1383000 IL

Re: K180643
Trade/Device Name: MedCu Antibacterial Wound Dressings with Copper-Oxide (MedCu ABWDs)
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 20, 2018
Received: October 23, 2018

Dear Tali Hazan:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kimberly Ferlin -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180643

Device Name
MedCu Antibacterial Wound Dressings with Copper-Oxide
(also identified as MedCu ABWDs)

Indications for Use *(Describe)*
The MedCu Antibacterial Wound Dressings with Copper-Oxide are indicated for the management of wounds and to provide a physical bacterial barrier (adhesive contour type only). The dressings are applied topically and are in direct contact with the wound. The dressings are intended to be used for indications as follows:

Over-The-Counter (OTC) use indications:
Local management of superficial wounds, minor burns, abrasions and lacerations (tears).

Prescription use indications (Rx-only):
- Partial and full thickness wounds,
- Pressure ulcers (stage I-IV),
- Diabetic ulcers,
- Venous stasis ulcers,
- Arterial ulcers,
- 1st and 2nd degree burns,
- Surgical wounds,
- Vascular access or peripheral IV sites,
- Orthopedic external pin sites, and
- Acute wounds such as lacerations, abrasions, and skin tears.

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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510(K) SUMMARY FOR MEDCU ANTIBACTERIAL WOUND DRESSINGS WITH COPPER-OXIDE (ABWDS)

DATE PREPARED: November 11, 2018

1. 510(K) OWNER NAME

Company Name: MedCu Technologies Ltd.
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2. DEVICE NAME

Common/Usual Name: Wound Dressings
Proprietary/Trade name: MedCu Antibacterial Wound Dressings with Copper-Oxide (also identified as MedCu ABWDs)
Classification: The MedCu Antibacterial Wound Dressings with Copper-Oxide are unclassified medical devices under the following classification names:

Classification Name	Product Code	21 CFR Ref.	Panel
Dressing, Wound, Drug	FRO	Pre-Amendment, Unclassified	General and Plastic Surgery

3. PREDICATE DEVICES

MedCu Antibacterial Wound Dressings with Copper-Oxide are substantially equivalent to the following Predicate Devices:

3.1 Argentum Medical's *Silverlon® Wound Pad Dressing & Silverlon® Island Wound Dressing*, cleared under 510(k) number **K143001** at November 7, 2014;

3.2 ProCyte Corporation's *Lamin® Wet Dressing (Copper-Saline)*, cleared under 510(k) number **K964468** at February 3, 1997.

4. DEVICE DESCRIPTION

The MedCu Antibacterial Wound Dressings with Copper-Oxide are sterile, soft, single use, barrier wound dressings composed of an internal absorbent layer and one or two external nonwoven layers (only the adhesive contour model serves as physical barrier). The external layer(s) are made of Polypropylene nonwoven fabric and the internal layer is made of needle punch layer made of Polyester and Cellulose fibers. The wound dressings achieve at least 500% fluid absorbency.
Both the internal and external layers are impregnated with copper-oxide particles. The one or two external layers cover the internal layer from one or both sides, accordingly. The wound dressing size is of 10 cm x 10 cm or 5 cm x 5 cm (other variations may be included as well), and may be provided with or without an adhesive contour (adhesive border), which provides physical bacterial barrier. The wound dressings without an adhesive contour can be cut per wound shape. The Copper-Oxide ions are released within the wound dressing from the polymeric matrix of each layer in the presence of moisture. The MedCu ABWDs, reduced the tested bacteria by more than 4 log within the wound dressing based on in-vitro testing.

MedCu ABWDs absorb wound fluid, contain copper-oxide to inhibit bacterial growth within the dressing and serves as a *barrier against bacterial penetration.
**Note:* *Barrier against bacterial penetration is achieved only by the adhesive contour model.*

The wound dressing is provided sterile and kept sterile in a sterilization pouch for its entire shelf life.
Body contact materials were evaluated for biocompatibility with accordance to FDA's Guidance document for *Use of ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing with a Risk Management Process,* dated June 16, 2016 and the ISO 10993-1:2009 standard.

5. INTENDED USE

The MedCu Antibacterial Wound Dressings with Copper-Oxide are indicated for the management of wounds and to provide a physical bacterial barrier (adhesive contour type only). The dressings are applied topically and are in direct contact with the wound. The dressings are intended to be used for indications as follows:

Over-The-Counter (OTC) use indications:
Local management of superficial wounds, minor burns, abrasions and lacerations (tears).

Prescription use indications (Rx-only):

- Partial and full thickness wounds,
- Pressure ulcers (stage I-IV),
- Diabetic ulcers,
- Venous stasis ulcers,
- Arterial ulcers,
- 1st and 2nd degree burns,
- Surgical wounds,
- Vascular access or peripheral IV sites,
- Orthopedic external pin sites, and
- Acute wounds such as lacerations, abrasions, and skin tears.

6. TECHNOLOGICAL CHARACTERISTICS

The MedCu non-adherent Antibacterial Wound Dressings with Copper-Oxide are impregnated with copper-oxide particles, which serve as an antibacterial agent to achieve log reduction of at least 4 log of wide range of bacteria within the wound dressing.
The device containing adhesive contour also serves as a bacterial barrier to confer additional protection to the wound.

The wound dressings' non-adherent external layer reduces pain during dressing removal.

7. PERFORMANCE DATA

MedCu Antibacterial Wound Dressings with Copper-Oxide have been successfully tested through laboratory non-clinical tests to support the safety and effectiveness of the device and the determination of substantial equivalence with predicate devices.
MedCu conducted the following tests:

7.1 Chemical and biological tests according to ISO 10993-1, ISO 10993-12, ISO 10993-18 and FDA Guidance document for Biological Evaluation June 2016: *Exhaustive extractions, FTIR, GC-MS, ICP-OES, UPLC-MS, Cytotoxicity, Skin irritation and Intracutaneous reactivity, Acute systemic toxicity, Sensitization (Maximization), Wound healing study on large animal (porcine).*

7.2 Antibacterial effectiveness testing per AATCC 100 following real-time aging products showing more than 4 log reduction of viable titers of 6 bacteria for the device intended use duration. The bacteria tested are: *E. coli, E. faecalis, E. aerogenes, K. pneumoniae, S. epidermis* and MRSA.

7.3 Bacterial barrier effectiveness for the device intended use duration (adhesive contour model only).

7.4 Absorbance capacity of at least 500% of the wound dressing weight.

7.5 Copper Oxide particles size and shape analyses using ICP (Inductively Coupled Plasma), SEM (Scanning Electron Microscopy) and EDS (Energy Dispersive X-ray Spectrometry) analyses.

7.6 Copper Oxide particle size distribution using DLS (Dynamic Light Scattering) method.

7.7 Copper Oxide leachables in order to determine if copper oxide particles were released from the antibacterial wound dressing, using DLS method.

7.8 MEC (Minimal Effective Concentration) study evaluating the minimal effective concentration required to achieve at least 4 log reduction of the tested microorganisms.

7.9 Packaging shelf life using accelerated aging method according to ISO 11607-1.

7.10 Sterilization validation using EtO half cycle method according to ISO 11135:2014, including EtO/ECH residuals according to ISO 10993-7:2008.

7.11 Pyrogenicity test using LAL method and Material-Mediated Pyrogen study.

Tests results support all MedCu's antibacterial wound dressing labeling claims in order to establish substantial equivalency.

8. SUBSTANTIAL EQUIVALENCE

MedCu Antibacterial Wound Dressings with Copper-Oxide is substantial equivalent to the predicate devices selected in terms of indication for use, technology, performances, patient population and nature of body contact.

The substantial equivalent decision was received based on the following comparison with the predicate devices:

Feature	Silverlon® Wound Pad Dressing & Silverlon® Island Wound Dressing Primary Predicate Device Cleared under K143001	ProCyte Corp. Lamin® Wet Dressing (Copper Saline) Reference Predicate Device Cleared under K964468	MedCu Antibacterial Dressing with Copper-Oxide - Subject Device -
Indication for use	Silverlon® Island Wound Dressing and Silverlon® Wound Pad Dressing are multi-layer, sterile, non-adherent, antimicrobial barrier wound dressings **for The Over-The-Counter Indications:** Local management of superficial wounds minor burns abrasions and lacerations. **and for Prescription Indications:** Under the supervision of a healthcare professional Silverlon® Island Wound Dressings and Silverlon® Wound Pad Dressings are intended for up to 7 day use for wounds such as vascular access or peripheral IV sites, orthopedic external pin sites, wound drain sites, surgical wounds (donor and graft sites, incisions), partial to full thickness dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers).	The device is a hydrogel for the dressing and management of both graft recipient and donor sites, postoperative incisions, pressure ulcers, diabetic ulcers, stasis ulcers, 1st and 2nd degree burns, arterial ulcers, pressure sores, and skin conditions associated with peristomal care. The dressing is intended to cover a wound or burn on a patient's skin, provide a moist wound environment, absorb wound exudate, and protect against abrasion, friction, desiccation, and contamination.	The MedCu Antibacterial Wound Dressings with Copper-Oxide are indicated for the management of wounds and to provide a physical bacterial barrier. The dressings are applied topically and are in direct contact with the wound. The dressings are intended to be used for indications as follows: **Over-The-Counter (OTC) use indications:** Local management of superficial wounds, minor burns, abrasions and lacerations (tears). **Prescription use indications (Rx-only):** Partial and full thickness wounds, pressure ulcers (stage I-IV), diabetic ulcers, venous stasis ulcers, arterial ulcers, 1st and 2nd degree burns, surgical wounds, vascular access or peripheral IV sites, orthopedic external pin sites, and acute wounds such as lacerations, abrasions, and skin tears.

Feature	Silverlon® Wound Pad Dressing & Silverlon® Island Wound Dressing Primary Predicate Device Cleared under K143001	ProCyte Corp. Lamin® Wet Dressing (Copper Saline) Reference Predicate Device Cleared under K964468	MedCu Antibacterial Dressing with Copper-Oxide - Subject Device -
Prescription / OTC	Both prescription and OTC	Unknown	Both prescription and OTC
Design	4 (Pad) or 5 (Island) Layers: • Layer 1 – no-adherent knitted nylon fiber coated with metallic silver • Layer 2 - polyethylene film used to bond the nylon substrate to the Layer 3; • Layer 3 - absorptive laminate pad • Layer 4 - polyethylene film that bonds the pad to Layer 5, • Layer 5 – adhesive polyester fabric	1- Layer of cotton-blend non-woven gauze saturated with copper saline	2- or 3-layer: • Internal layer made of absorbent cellulose and polyester layer containing copper-oxide • one or two external non-adherent nonwoven polypropylene layers containing copper-oxide
Dimensions	Multiple sizes including 10 cm x 10 cm and 5 cm x 5 cm	Unknown	10 cm x 10 cm, or 5 cm x 5 cm
Material	Nylon, polyethylene, polyester	Cellulose	Polypropylene, Polyester, Cellulose
Antimicrobial agent	Silver / Silver-oxide	Copper-saline	Copper-oxide
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Sterilization	Sterile (EtO)	Sterile	Sterile (EtO)
Principle of operation	Antimicrobial effect is achieved via the released silver ions within the dressing in moist environment	Copper saline dressing provides a moist wound environment and protects the wound	Antibacterial effect is achieved via the released copper ions within the dressing in moist environment
Technology	Only the layer in contact with the skin is made of nylon fiber covered (coated) with silver	Copper saline wet dressing	All layers of the wound dressing are impregnated with copper-oxide

Feature	Silverlon® Wound Pad Dressing & Silverlon® Island Wound Dressing Primary Predicate Device Cleared under K143001	ProCyte Corp. Lamin® Wet Dressing (Copper Saline) Reference Predicate Device Cleared under K964468	MedCu Antibacterial Dressing with Copper-Oxide - Subject Device -
Adhesive / non-adhesive contour	Both	No	Both
Recommended dressing change	Up to 7 days	Unknown	Up to 7 days
Absorbency	65 oz/yd^2	Absorbs wound exudate	2 layers: ~79.4 oz/yd^2 3 layers: ~75.6 oz/yd^2
Single Use	Yes	Yes	Yes

Substantial Equivalence Discussion

As can be seen in the above comparison table, same claims are covered under the indications for use statement of MedCu proposed device as compared to both predicate devices.

Certain differences exist between the subject and predicate devices in terms of number of the dressing layers and antibacterial agent (silver used for Silverlon, while Lamin and MedCu are copper based).

Unlike Silverlon in MedCu ABWD the antibacterial agent exists in all layers (except for the adhesive contour layer, when such layer is included). This difference does not affect the intended purpose of the device or its safe use. The successful biocompatibility tests confirmed that the existence of the antibacterial agent throughout the entire dressing does not affect the safe use of the device. The ABWDs have an antibacterial effect within the dressing. This claim, which narrows the cleared Silverlon antimicrobial claim, does not affect the safe use of the device.

The predicate dressings' materials consist of biocompatible polymeric materials with and without cellulose. MedCu ABWD includes biocompatible polymeric materials and cellulose in all subject models. This difference does not alter the intended purpose of the device or its safe use since the intended use of both devices remains the same while MedCu chose to provide ABWDs only as absorbent wound dressings. The device was evaluated under full absorbency capacity simulating worst case clinical use and performed as intended.

All three dressings (two predicates and the subject device) absorb wound exudates, are provided sterile, biocompatible and intended for single use only.

The similarities and differences were thoroughly discussed within the 510(k) submission and it was concluded that the differences do not critically affect the intended clinical use and do not raise new questions of safety and effectiveness with regards to the proposed device.

In light of the above, we have concluded that substantial equivalence of the MedCu ABWD with the predicate devices was established.

9. CONCLUSIONS

After considering all substantial equivalency features of the predicate devices against the subject device, and after discussing similarities and differences of these features, we have concluded that MedCu ABWD (subject device) meets all proposed labeling claims and specification requirements. Certain differences between the predicate devices and the subject device were discussed and addressed within the 510(k) submission and found to be not significant in terms of safety and effectiveness. The evaluation of our device performances demonstrates that it is as safe and as effective as the predicate devices, and therefore the requirements of substantial equivalency are met.