October 8, 2020

EnzySurge Ltd.
% Daniel Albahari
Regulatory Consultant
BioReg Services
6 Beit HaShoeva St.
Jerusalem, 9751723
Israel

Re: K200767
Trade/Device Name: SilverStream Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 27, 2020
Received: September 2, 2020

Dear Daniel Albahari:

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/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 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 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,

Anjana Jain, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200767

Device Name
SilverStream Gel

Indications for Use *(Describe)*

Prescription Use
SilverStream Gel is intended for use under the supervision of a healthcare professional for management and moisturizing of wounds such as stage I-IV pressure ulcers, stasis ulcers, diabetic foot ulcers, post-surgical wounds, first and second-degree burns, cuts abrasions and minor skin irritations.

OTC Use
SilverStream Gel is intended for the management and moisturizing of minor cuts, minor burns, abrasions and irritated areas.

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 K200767

510(K) Number K200767

Applicant's Name: EnzySurge Ltd.
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Date Prepared: October 8th, 2020

Trade Name: SilverStream Gel

Classification Name: Dressing, Wound, Drug

Product Code: FRO

Device Classification: Unclassified

Panel: General & Plastic Surgery

Predicate Device: SilverStream® [K093227]

Intended Use / Indication for Use:

Prescription Use

SilverStream Gel is intended for use under the supervision of a healthcare professional for management and moisturizing of wounds such as stage I-IV pressure ulcers, stasis ulcers, diabetic foot ulcers, post-surgical wounds, first and second-degree burns, cuts abrasions and minor skin irritations.

OTC Use
SilverStream Gel is intended for the management and moisturizing of minor cuts, minor burns, abrasions and irritated areas.

Device Description:
SilverStream Gel is a clear hypertonic, non-pyrogenic liquid gel, designed for the management and moisturizing of wounds such as stage I-IV pressure ulcers, stasis ulcers, diabetic foot ulcers, post-surgical wounds, first and second-degree burns, cuts abrasions, minor skin irritations, minor cuts, minor burns, abrasions and irritated areas.

The action of SilverStream Gel is achieved by moisturizing wounds and maintaining wound moisture between dressing changes. A maintaining of the moist environment in the wound has been shown to be conducive to wound healing. Silver, serves as a preservative which, based on in vitro testing, inhibits the growth of microorganisms within the product during the shelf storage.

The SilverStream Gel is supplied in 60mL polyethylene terephthalate (PETG) bottles. A pump head for dispensing is also supplied.

Substantial Equivalence:
SilverStream Gel has the same indication for use (both Rx and OTC) as the predicate device. Both SilverStream® and SilverStream Gel are intended for the management and moisturizing of wounds. Primarily, in similarity to SilverStream®, SilverStream Gel helps to moisturize wounds and maintains a moist wound environment that is conducive to healing.

In addition, the SilverStream Gel has essentially similar technological characteristics, including principles and mode of operation, as its predicate device.
Both SilverStream Gel and SilverStream® solution use the same ingredients, and they differ in formulation by the presence of the inactive ingredient Carbopol, which has been added for the purpose of providing viscosity to the gel formulation.

The SilverStream Gel, the predicate device as well as the reference devices contain silver, which acts as a preservative which, based on in vitro testing, inhibits the growth of microorganisms within the product during the shelf storage.
In summary, the intended use and indications for use of the SilverStream Gel are the same as the intended use and indications for use of its predicate device, SilverStream®. Further, the technological characteristics and principles of operation of SilverStream Gel are substantially similar to those of the claimed predicate device and any minor differences in

technology due to more viscous formulation as compared to solution do not raise new questions of safety or effectiveness.

Performance Data:
Representative samples of the device underwent testing including bench testing - Antimicrobial Preservative Effectiveness Testing; Microbial Limits; and silver concentration.

The safety and efficacy are also demonstrated by biocompatibility tests in accordance with the FDA biocompatibility guidance issued on June 16, 2016 and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The gel is considered a breached/compromised surface device with prolonged contact and testing included cytotoxicity, irritation, sensitization, systemic toxicity, material mediated pyrogenicity, porcine wound healing study and repeated subcutaneous toxicity rat study.

Visual inspection, viscosity, pH, menthol and silver concentration, microbial count, and Bacterial Endotoxin testing (LAL) were all tested as part of shelf life testing.

SilverStream Gel meets its specification and has been shown to be substantially equivalent to the predicate device.

Conclusion:
EnzySurge has submitted information on indication for use, design and principle of operation, biocompatibility and performance characteristics to establish that the SilverStream Gel is substantially equivalent. It was concluded that the intended use, indications for use and technological characteristics of the SilverStream Gel are substantially equivalent to SilverStream (K093227) and there were no new questions of safety or effectiveness. Therefore, SilverStream Gel is substantially equivalent to the predicate device.