DEC 10 2009

510(K) SUMMARY

510(K) Number K K093227

5.1 Applicant's Name: EnzySurge Ltd.
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5.3 Date Prepared: December 2009

Trade Name: SilverStream (for Prescription Use)
DermaSept (for Over the Counter Use)

5.4 Classification Name: Dressing, Wound, Drug

5.5 Product Codes: FRO

5.6 Device Class: Class II

5.7 Regulation Number: unclassified

5.8 Panel: General & Plastic Surgery

5.9 Predicate Devices:

3. Anasept™ Antimicrobial Skin and Wound Cleanser (AnaCapa Technologies Inc.); cleared under K073547.
4. Silvaklenz Antibacterial Silver Skin & Wound Cleanser (Medical Molecular Therapuetics LLC); cleared under K063069

5.15 Intended Use / Indication for Use:

Prescription Use: SilverStream 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

Over-The-Counter Use: DermaSept is intended for the management and moisturizing of minor cuts, minor burns, abrasions and irritated areas

5.16 Device Description:

The SilverStream (prescription), and DermaSept (OTC) Solutions, are clear, hypertonic aqueous solutions designed for the management and moisturizing of the application site by the action of the fluid moving across the wound bed. The product is hypertonic and contains a surfactant. The SilverStream, and DermaSept, Solution contains an antimicrobial ionic silver, as a preservative, which has been shown, by in vitro testing, to inhibit the growth of microorganisms such as Eschericha coli, Staphylococcus epidermidis, Staphylococcus aureus, Klebsiella pneumoniae Pseudomonas aeruginosa, Candida albicans and Aspergillus niger.

5.17 Substantial Equivalence:

Intended Use and Indications for Use

The SilverStream labeled for prescription use, has a similar intended use and the same indications for use as the predicates, i.e., all devices are used in the management of wounds. The DermaSept, labeled for OTC use, also has a similar intended use and indications for use as its predicates. Therefore the SilverStream and the DermaSept can be considered substantially equivalent to the predicate devices with regard to the intended use.

Technological Characteristics

The SilverStream, and DermaSept, has substantially similar technological characteristics, including principles and mode of operation, to the predicate devices. Primarily, in similarity to the predicate devices, the SilverStream and DermaSept, is a solution that moves across the wound surface (flushing).

In addition, the SilverStream, DermaSept, and the predicate devices all contain an antimicrobial agent that inhibits the growth of microorganisms.

Performance Testing

A set of in vitro and in vivo biocompatibility tests were performed in order to demonstrate the safety and performance of the SilverStream and DermaSept. The available performance data demonstrate substantial equivalence of the SilverStream, and DermaSept, to predicates and that there are no new issues of safety and effectiveness.

Summary

The SilverStream, and DermaSept have similar intended uses and indications, technological characteristics and principles of operation as the predicate devices. Based on the performance testing results and the analysis of the similarities and differences, EnzySurge Ltd believes SilverStream and DermaSept are substantially equivalent to the predicates and do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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DEC 10 2009

Re: K093227
Trade/Device Name: SilverStream (prescription); DermaSept (OTC)
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 12, 2009
Received: October 14, 2009

Dear Dr. Shtiegman:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K093227

Device Name: SilverStream (for Prescription Use)

Indications for Use:

Prescription Use

SilverStream 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.

Prescription Use __√_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093227

INDICATIONS FOR USE

510(k) Number (if known): K093227

Device Name: DermaSept (for Over the Counter Use)

Indications for Use:

Over-The-Counter Use:

DermaSept is intended for the management and moisturizing of minor cuts, minor burns, abrasions and irritated areas.

Prescription Use _____ AND/OR Over-The-Counter Use __√___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

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