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K063069

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## 7. 510(k) Summary Information

### 7.1 Submitter's Name and Address

Medical Molecular Therapeutics LLC  
Arthur B. Flick MD  
36 Lake Rabun Road  
Lakemont, Georgia 30552

Contact Person: A. B. Flick MD  
Telephone: 706 782 5064  
Email: abflick@alltel.net

### 7.2 Date Prepared

20 August 2006

### 7.3 Device Name

Trade Name: Silvaklenz™ Antibacterial Silver Skin & Wound Cleanser  
Common Name: Silvaklenz™  
Classification Name: Liquid Bandage KMF

### 7.4 Predicate Devices 807.92(a)(3)

Dermacyn Wound Cleanser	K042729
Restore Wound Cleanser	K022670
X-Static Silverseal Hydrogel Wound Dressing	K040019
Acryderm Silver Antimicrobial Wound Gel	K011994
Antimicrobial Barrier Wound Contact Dressing	K023612

## 7.5 Device Description

A buffered skin and wound cleansing solution that is intended for the external cleansing of dermal wounds and skin. The mechanical action of the fluid moving across the skin or wound surface provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris. The product contains a surfactant (soap), cocamidopropyl betaine, to assist with the removal foreign material such as dirt and debris. After application the wound is rinsed with water or normal saline. The Silvaklenz Antibacterial Silver Skin & Wound Cleanser is clear, odorless and colorless. The product is available in 2 oz, 4 oz, 8 oz and 16 oz spray bottles.

## 7.6 Assessment of Performance Data

Silvaklenz Antibacterial Silver Skin & Wound Cleanser has been subject to *in vitro* and *in vivo* biocompatibility (ISO Modified Intracutaneous Study, the USP and ISO Modified Systemic Toxicity Study and the ISO Maximization Sensitization) and cytotoxicity testing (Agarose Overlay Method). These tests support the safe use of Silvaklenz Antimicrobial Silver Skin & Wound Cleansing Solution in contact with breached or compromised skin. *In vitro* Antimicrobial testing was assessed by the standard the MIC and MBC Dilution Methods, Zone of Inhibition, USP Antimicrobial Effectiveness Test <51>, USP Microbial Limit Test <61>, Bioburden Aerobic Total Count and Microbial Challenge Test.

## 7.7 Statement of Intended Use

OTC: For normal skin and minor wounds, ulcerations and burns, abraded skin, and irritated areas. Aids in removal of excessive skin oils, dirt and debris. Effective cleansing action.

Professional: To cleanse, moisten and irrigate dermal lesions; Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations.

## 7.8 Technological Characteristics and Substantial Equivalence

Silvaklenz Antibacterial Silver Skin & Wound Cleanser is a combination

product within the meaning of section 503(g) of the Federal Food, Drug, and Cosmetic Act (Act) and Title 21 of the Code of Federal Regulations (CFR) section 3.2(e)(1) and (2). In accordance with section 503(g)(1) of the Act and 21 CFR section 3.4, Silvaklenz Antibacterial Silver Skin & Wound Cleanser had three modes of action. One mode of action of the product is that of the device components (the pump-spray and the remaining ingredients of the aqueous solution) mechanically remove debris, necrotic tissue and foreign particles from the skin and wound surface. A second mode of action of the product is that of the cocamidopropyl betaine (drug component) reduces the surface tension and thereby assist with mechanical cleansing and debridement. A third mode of action is ionic silver (drug component) that functions as an antimicrobial agent.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Medical Molecular Therapeutics, LLC  
% Arthur B. Flick, MD  
36 Lake Rabun Road  
Lakemont, Georgia 30552

Re: K063069

Trade/Device Name: Silvaklenz Antibacterial Silver Skin & Wound Cleanser

Regulatory Class: Unclassified

Product Code: FRO

Dated: June 7, 2007

Received: June 11, 2007

Dear Dr. Flick:

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 such 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.

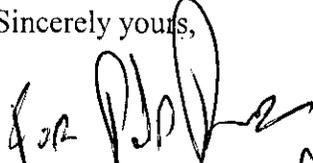
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally

marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

*Handwritten notes:*  
R. [unclear] DR  
7/13/02

Enclosure

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## 5. INDICATIONS FOR USE

Device Name: Silvaklenz Antibacterial Silver Skin & Wound Cleanser

For the Over-The-Counter Indications:

For normal skin and minor wounds, ulcerations and burns, abraded skin, and irritated areas. Aids in removal of excessive skin oils, dirt and debris. Effective cleansing action.

For Professional Prescription Indications:

To cleanse, moisten and irrigate skin and dermal lesions; Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use   X    
(21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number   12063069