Company:	Anacapa™ Technologies, Inc. 301, E. Arrow Hwy, suite 106 San Dimas, CA 91773
Contact :	Ila Doshi , Official FDA Correspondent Telephone: 909-394-7795 Fax: 909-394-9895 Email: ila@anacapatechnologies.net
Date of Preparation:	Nov. 10, 2006
Device Name (proprietary):	Silver Shield™ Antimicrobial Skin and Wound Gel
Common Name:	Moist Antimicrobial wound filler OR Amorphous Hydrogel Wound Dressing
Classification Name:	Dressing, wound and burn, hydrogel w/drug and/or biologic
Classification:	Unclassified
Product Code:	MGQ

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Legally Marketed Devices for substantial equivalence comparison:
Silver Shield Antimicrobial Skin and Wound Gel is substantially equivalent to AcryDerm Silver Antimicrobial Wound Gel, 510(K) # **K011994**. (AcryMed, Inc., OR also distributed under the trade name SilvaSorb™ Gel, Silver Antimicrobial Wound Gel (Medline Industries, Inc.)

Description of Device:
Silver Shield Antimicrobial Skin and Wound Gel is a clear, amorphous hydrogel wound dressing that helps maintain a moist wound environment that is conducive to healing, by either absorbing the wound exudates or donating the moisture while delivering antimicrobial silver. The gel matrix of the Silver Shield™ Antimicrobial Skin and Wound Gel is composed of a silver complex and an inert viscosity-modifying agent that imparts viscous hydrogel properties. Silver Shield™ Antimicrobial Skin and Wound Gel will be supplied in collapsible blind ended, heat-sealed, co-extruded tubes fitted with a "flip top" dispenser closure. This reusable tube will be placed in a chipboard dispenser box with a package insert.

Intended Use of the Device:
Silver Shield Antimicrobial Skin and Wound gel is a clear, amorphous hydrogel wound dressing which functions as a long lasting antimicrobial barrier by inhibiting the growth of common bacteria such as: *Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Proteus mirabilis, Serratia marcescens,* including antibiotic resistant strains: *MRSA & VRE,* as well as fungi such as *Candida albicans and Aspergillus niger.* Silver Shield™ Antimicrobial Skin and Wound Gel is intended for OTC use for Abrasions and lacerations and under the supervision of a health care professional in the management of Stage 1-1V Pressure Ulcers, Partial and Full thickness Wounds, Diabetic Foot and Leg Ulcers, Grafted and donor sites

Device Technological Characteristics:

Silver Shield™ Antimicrobial Skin and Wound Gel exhibits the capacity to absorb moisture and control light wound exudate. Antimicrobial activity is embodied in the content of silver contained in Silver Shield™ Antimicrobial Skin and Wound Gel. The antimicrobial silver inhibits the growth of microorganisms and thus acts as a preservative that controls the microbial contamination of the product as well as acts as an antimicrobial barrier and thus prevents microbiological contamination of the application site that may help reduce infection. Hydrogel characteristics are imparted by an inert viscosity enhancing agent rather than "hydrophilic polyacrylate absorbent microspheres" contained in the predicate device (AcyrDerm Silver Antimicrobial wound Gel, Acrymed, Inc., OR; AKA Silvasorb™ Antimicrobial Wound Gel, 510(K) # K011994) . Silver Shield™ Antimicrobial Skin and Wound Gel represents substantial equivalence to the predicate device.

Manufacturing:

Silver Shield™ Antimicrobial skin and Wound Gel will be manufactured according to product specifications and under the guidelines of Good Manufacturing Practices (GMP). Risk analysis has been performed to identify possible failure mode during manufacturing. Manufacturing controls have been developed and implemented to address the identified risk factors based on the criticality of the failure mode. All established GMPs will assure that the device manufactured at Anacapa™ Technologies, Inc meets all the established specification prior to release and is safe and effective for its intended use.

Performance Testing:

USP preservative efficacy testing was performed to establish that Silver Shield Antimicrobial skin and Wound Gel is an effective antimicrobial barrier. The test was performed using the test organisms in accordance with USP and some additional bacterial strains such as antibiotic resistant Methicillin Resistant Staphylococcus aureus (MRSA), and Vancomycin resistant Enterococcus (VRE).
Various test models were used for determining the anti-micorbial barrier properties. All tests have met or exceeded the requirements as set forth in USP for preservative efficacy test as well as the testing performed for the predicate device K011994

Substantial Equivalence discussion:

The indications of use, technological properties, performance testing described above, for the Silver Shield Antimicorbial Skin and Wound Gel are substantially equivalent to those of predicate device AcyrDerm Silver Antimicrobial wound Gel, Acrymed, Inc., OR; AKA Silvasorb™ Antimicrobial Wound Gel, 510(K) # K011994. The performance testing exceeds the requirements as set forth by USP as well exceeds those demonstrated by the predicate device. The biocompatibility testing and the performance testing performed for the device also demonstrated that the device is safe and effective for the indications of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Anacapa Technologies, Inc.
% Ms. Ila Doshi
301 East Arrow Highway, Suite 106
San Dimas, California 91773

NOV 2 1 2006

Re: K062212
Trade/Device Name: Silver Shield™ Antimicrobial Skin Wound gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 16, 2006
Received: October 18, 2006

Dear Ms. Doshi:

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.

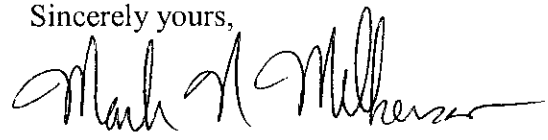
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Enclosure

Device Name: Silver Shield™ Antimicrobial Skin Wound gel

Indications for use:

Silver Shield™ Antimicrobial Skin and Wound Gel is intended for OTC use for Abrasions and lacerations and under the supervision of a health care professional in the management of Stage 1-1V Pressure Ulcers, Partial and Full thickness Wounds, Diabetic Foot and Leg Ulcers, Grafted and donor sites,

Prescription Use ___ℓ___ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Mark A Milkerson

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

510(k) Number K062212

Concurrence of CDRH, Office of Device Evaluation (ODE)