Company: Anacapa™ Technologies, Inc.
301, E. Arrow Hwy, suite 106
San Dimas, CA 91773

Contact : Ila Doshi , Official FDA Correspondent
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APR 23 2008

Date of Preparation: April 2, 2008

Device Name (proprietary): Anasept™ Antimicrobial Skin and Wound Gel

Common Name: Moist anti-microbial wound filler OR
Amorphous Hydrogel Wound Dressing

Classification Name: Dressing, wound and burn, hydrogel w/drug and/or biologic

Classification: Unclassified

Product Code: FRO

Legally Marketed Devices for substantial equivalence comparison:

Anasept™ Antimicrobial Skin and Wound Gel is substantially equivalent to Silver Shield™ Antimicrobial Skin and Wound Gel 510(K) # **K062212 manufactured and distributed by Anacapa™ Technologies, Inc**

Description of Device:

Anasept™ Antimicrobial Skin and Wound Gel is a clear, amorphous, isotonic hydrogel wound dressing that helps maintain a moist wound environment that is conducive to healing, by either absorbing wound exudate or donating moisture while delivering antimicrobial sodium hypochlorite. This antimicrobial agent inhibits the growth of microorganisms. Anasept™ Antimicrobial Skin and Wound Gel will be supplied in collapsible blind ended, heat-sealed, co-extruded tubes fitted with a "flip top" dispenser closure. The labeling of the product will be silk screened on the tube. (See proposed labeling section I for the content of the label)

Intended Use of the Device:

OTC: Anasept™ Antimicrobial Skin and Wound Gel is intended for OTC use for management of skin abrasions, lacerations, minor irritations, cuts, exit sites and intact skin.
Professional Use: Anasept™ Antimicrobial Skin and Wound Gel is intended to be used under the supervision of a healthcare professional in the management of wounds such as stage I-IV pressure ulcers, partial and full thickness wounds, diabetic foot and leg ulcers, post surgical wounds, first and second degree burns, grafted and donor sites.

These indications are similar to the predicate device 510(K) # K062212

Device Technological Characteristics:

Anasept™ Antimicrobial Skin and Wound Gel is a clear, amorphous, isotonic hydrogel that helps maintain a moist wound environment that is conducive to healing, by either absorbing wound exudate or donating moisture while delivering antimicrobial sodium hypochlorite. Anasept™ Gel inhibits the growth of bacteria such as *Staphlyococcus aureus, Psuedomonas aeruginosa, Escherichia coli, Proteus mirabilis, Serratia marcescens*, *Acinetobacter baumannii*, antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA), and Vancomycin resistant *Enterococcus faecalis* (VRE) that are commonly found in the wound bed, as well as, fungi such as *Candida albicans* and *Aspergillus niger.*
Hydrogel characteristic of Anasept™ Antimicrobial Skin and Wound Gel is imparted by an inert viscosity enhancing agent.
It should also be noted that Anasept™ Antimicrobial Skin and Wound Gel has been in the commercial market since May 2005 as an OTC drug product (NDC # 67180-500-03, catalog # 5003G) for the same indications for wound management without any untoward reports regarding safety, efficacy, stability and/or overall stability of the product.

Manufacturing:

Anasept™ 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 specifications prior to release and is safe and effective for its intended use.

Performance Testing:

Anasept™ Antimicrobial Skin and Wound Gel has been subjected to in-vitro and in-vivo biocompatibility studies to demonstrate that the device is safe for the indications for use. Time/Kill studies were performed in accordance with the procedure provided with the original submission. The tests were performed utilizing the test organisms prescribed in the USP Antimicrobial Effectiveness Testing <51> such as *Staphylococcus aureus, Psuedomonas aeruginosa, Escherichia coli, Candida albicans, Aspergillus niger* and additional bacterial strains, such as, *Proteus mirabilis, Serratia marcescens* and *Acinetobacter baumannii* and antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus faecalis* (VRE), that are commonly found in wound bed. All test results indicate that product is very capable of inhibiting the growth of bacteria and reducing high level concentrations (10^7 /gram of product) of microorganisms to undetectable levels.
Stability studies have been performed on the product to demonstrate the product is stable and effective for the entire shelf life.

Substantial equivalence conclusion:
The indications of use, technological properties, performance testing described above, for the Anasept™ Antimicrobial Skin and Wound Gel are substantially equivalent to those of predicate device Silver Shield™ Silver Antimicrobial Skin and Wound Gel. They both are used in the management of wounds, they both contain same viscosity enhancer and they both contain an antimicrobial ingredient that exhibits the broad spectrum antimicrobial properties.

Device Technological Characteristics:

Anasept™ Antimicrobial Skin and Wound Cleanser is a clear, isotonic liquid that helps in the mechanical removal of the debris and foreign material from the application site. Dirt, debris and foreign materials are mechanically removed by the action of the fluid (Wound Cleanser) moving across the wound bed or application site. Anasept™ Antimicrobial Skin and Wound Cleanser contains a broad spectrum antimicrobial agent sodium hypochlorite. It inhibits the growth of bacteria such as *Staphlyococcus aureus, Psuedomonas aeruginosa, Escherichia coli, Proteus mirabilis, Serratia marcescens*, including antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus faecalis* (VRE) and Acinetobacter baumannii, that are commonly found in wound bed as well as fungi such as *Candida albicans* and *Aspergillus niger*.

Manufacturing:

Anasept™ Antimicrobial Skin and Wound Cleanser will be manufactured under the guidelines of Good Manufacturing Practices (GMPs) and according to the established manufacturing, quality and product specifications. Batching Process Validation has been completed for this device and filling process parameters have been qualified after performing risk analysis for identification of 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 specifications prior to release and is safe and effective for its intended use.

Performance Testing:

Anasept™ Antimicrobial Skin and Wound Cleanser has been subjected to in-vitro and in-vivo biocompatibility studies to demonstrate that the device is safe for the indications for use.
The tests were performed utilizing the test organisms prescribed in the USP Antimicrobial Effectiveness Testing <51> such as *Staphylococcus aureus, Psuedomonas aeruginosa, Escherichia coli, Candida albicans, Aspergillus niger* and additional bacterial strains, such as, antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus faecalis* (VRE), *Proteus mirabilis, Serratia marcescens* and *Acinetobacter baumannii* that are commonly found in wound bed. All test results indicate that product is very capable of inhibiting the growth of bacteria and reducing high level concentrations of microorganisms (10^7 organisms /gram of product) to undetectable levels.
The results of the stability studies support the two years shelf life of the product.

Substantial Equivalence Conclusion:

As discussed in this 510(K) submission, Anasept™ Antimicrobial Skin and Wound Cleanser is similar in function and intended use as the predicate devices Dermacyn™ Wound Cleanser, 510(K) # K042729, and Silvaklenz™ Antibacterial Silver Skin and Wound Cleanser, K063069. The safety evaluation meets the requirements as set forth by USP and ISO. The indications of use, device description and performance testing described above and in this 501(K) submission concludes that Anasept™ Antimicrobial Skin and Wound Cleanser is substantially equivalent to predicate devices, Dermacyn™ Wound Cleanser, 510(K) # K042729, and Silvaklenz™ Antibacterial Silver Skin and Wound Cleanser, K063069.

Device Description:

Anasept™ Antimicrobial Skin and Wound Cleanser is a clear, isotonic liquid that helps in the mechanical removal of the debris and foreign material from the application site. Dirt, debris and foreign materials are mechanically removed by the action of the fluid (Wound Cleanser) moving across the wound bed or application site. The device also contains an antimicrobial agent that inhibits the growth of microorganisms. Anasept™ Antimicrobial Skin and Wound Cleanser will be supplied in High Density Polyethylene bottles in various packaging configuration: 15 oz in HDPE bottle with dispensing caps and 8, & 12 oz with Trigger sprayer and 8 oz with Finger pump sprayer.

Intended Use of the Device:

OTC: Anasept™ Antimicrobial Skin and Wound Cleanser is intended for OTC use for mechanical cleansing and removal of dirt, debris and foreign material from skin abrasions, lacerations, minor irritations, cuts, exit sites and intact skin.
Professional Use: Anasept™ Antimicrobial Skin and Wound Cleanser is intended for use under the supervision of a healthcare professional for mechanical cleansing and removal of foreign material including micro-organisms and debris from wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, grafted and donor sites.

Device Technological Characteristics:

Anasept™ Antimicrobial Skin and Wound Cleanser is a clear, isotonic liquid that helps in the mechanical removal of the debris and foreign material from the application site. Dirt, debris and foreign materials are mechanically removed by the action of the fluid (Wound Cleanser) moving across the wound bed or application site. The device Anasept™ Antimicrobial Skin and Wound Cleanser contains a broad spectrum antimicrobial agent sodium hypochlorite. It inhibits the growth of bacteria such as *Staphlyococcus aureus, Psuedomonas aeruginosa, Escherichia coli, Proteus mirabilis, Serratia marcescens*, including antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus faecalis* (VRE) and *Acinetobacter baumannii*, that are commonly found in wound bed, as well as, fungi such as *Candida albicans* and *Aspergillus niger*.

Performance Testing:

Time Kill tests were performed in accordance with the procedure provided with the orginal submission using the test organisms in accordance with USP Antimicrobial effectiveness test <51> such as, *Staphylococcus aureus, Psuedomonas aeruginosa, Escherichia coli, Candida albicans, Aspergillus niger*, and additional bacterial strains such as antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA), Vancomycin resistant *Enterococcus faecalis* (VRE), *Proteus mirabilis, Serratia marcescens* and *Acinetobacter baumannii,* that are commonly found in wound bed. Tests were performed in presence on bovine serum, an interfering substance that simulates the organic load conditions of a wound bed, and is known to inhibit the action of antimicrobial agents.
The test results clearly indicate that the product is capable of inhibiting the growth of bacteria and reducing high level concentrations of microorganisms (10^7 organisms/gram of product) to undetectable levels within fifteen minutes (Reduction by Log 7).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Anacapa Technologies, Inc.
% Ila Doshi
Director, Quality and Regulatory
Affairs
301 E. Arrow Highway, Suite 106
San Dimas, California 91773

Re: K073547
Trade/Device Name: Anasept™ Antimicrobial Skin and Wound Cleanser
Anasept™ Antimicrobial Skin and Wound Gel
Regulation Code: 21 CFR 880.5475
Regulation Name: Jet lavage
Regulatory Class: II
Product Code: FQH, FRO
Dated: March 11, 2008
Received: March 17, 2008

Dear Ila 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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

Enclosure

Device Name: Anasept™ Antimicrobial Skin and Wound Cleanser

Indications for use:

OTC: Anasept™ Antimicrobial Skin and Wound Cleanser is intended for OTC use for mechanical cleansing of dirt and debris form skin abrasions, minor irritations, cuts, exit sites and intact skin.

Professional Use: Anasept™ Antimicrobial Skin and Wound Cleanser is intended for professional use for cleansing and removal of foreign material including micro-organisms and debris from wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post surgical wounds, first and second degree burns, grafted and donor sites.

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 IF NEEDED)

Neil R P Ogden for mxm

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
510(k) Number K073547

Device Name: Anasept™ Antimicrobial Skin and Wound Gel

Indications for use:
OTC: Anasept™ Antimicrobial Skin and Wound Gel is intended for OTC use for management of Skin Abrasions and lacerations, minor irritations, cuts, exit sites and intact skin.
Professional Use: Anasept™ Antimicrobial Skin and Wound Gel is intended to be used by health care professionals for the management of wounds such as Stage I-IV Pressure Ulcers, Partial and Full thickness Wounds, Diabetic Foot and Leg Ulcers, Post Surgical Wounds, First and Second Degree Burns, Grafted and Donor Sites.

Prescription Use X 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)

Neil R Ogden for mxm
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K073547