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K082333

American Biotech Labs
A World Leader In Nano Silver Technology

APR - 2 2009

510(k) Summary

Submitter's Name and Address:	American Biotech Labs 780 West Canyon Crest Road Alpine, UT 84004
Contact Person:	William D. Moeller A Managing Director Phone: 801-756-1000 Fax: 801-756-5454
Date of Preparation:	March 20, 2009
Professional Trade Name:	ASAP Wound Dressing Gel
OTC Trade Name	ASAP Wound Dressing Gel
Device Common-Usual Name:	Wound Dressing Gel
Classification Number/Class	Unclassified

This 510(k) Summary is being submitted in accordance with the requirements of 21 C.F.R. 807.92.

The assigned 510(k) Number is: K082333

Predicate Devices:

Elta Silver Antimicrobial Wound Gel Dressing, WOU (K071703)
AcryDerm Silver Antimicrobial Would Gel (K011994 and K070333)
Silver Shield Antimicrobial Skin and Wound Gel (K062212)
Silveron® Adhesive Strip (K023609)
Actisorb Silver 220 Antimicrobial Binding Dressing (K022483)

Description of Device:

ASAP Wound Dressing Gel is an amorphous, water-based gel that contains silver hydrosol that may inhibit the growth of microorganisms within the dressing. The high moisture content gel contains a base matrix composed of hydrophilic and buffering compounds and contains silver from American Biotech Labs' proprietary silver hydrosol suspension. ASAP Wound Dressing Gel is supplied in a multi-dose gel pump and a tube (collapsible, low-density polyethylene tube, sealed on one end and fitted with a pop-open screw cap on the other end).

Indications for Use:

For the topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations

Technological Characteristics:

ASAP Wound Dressing Gel is an amorphous, water-based, gel that contains silver hydrosol. The composition of ASAP Wound Dressing Gel is substantially equivalent to the predicate devices listed above in that silver is the antimicrobial ingredient and moisture is managed using an aqueous base combined with a proper blend of hydrophilic substances. ASAP Wound Dressing Gel contains silver hydrosol that may inhibit the growth of microorganisms within the dressing. The product was evaluated through standard biological reactivity tests (ISO 10993) and found to be acceptable. Antimicrobial effectiveness was established through testing in accordance with USP <51>.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 2 2009

American Biotech Labs
% Swankin & Turner
Mr. James S. Turner
1400 16th Street, Northwest, Suite 101
Washington, District of Columbia 20036

Re: K082333
Trade/Device Name: ASAP Wound Dressing Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 24, 2009
Received: March 25, 2009

Dear Mr. Turner:

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 Fed-ral 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.

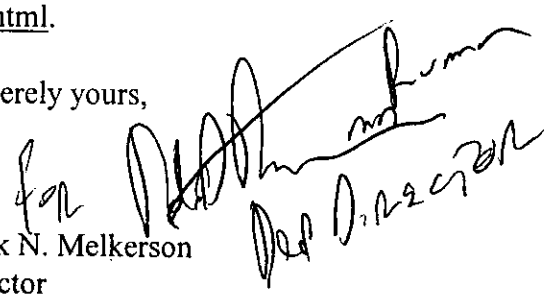
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(K) Number (if known): K082333

Device Name: ASAP Wound Dressing Gel

Over-the-Counter Indications for Use:

For the topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM 4/1/2009

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

510(k) Number K082333