510(k) SUMMARY

Reactive Skin Decontamination Lotion (RSDL)

Submitter Name:	U.S. Department of the Army
Submitter Address:	64 Thomas Johnson Drive Fort Detrick, Maryland 21702
Contact Person:	Ronald E. Clawson, Ph.D.
Phone Number:	301-619-2016
Fax Number:	301-619-7230
Date Prepared:	November 22, 2002
Device Trade Name:	Reactive Skin Decontamination Lotion (RSDL)
Device Common Name:	Kit, Decontamination
Classification Name:	MAC
Predicate Device:	K894455, U.S. Department of the Army, Decontaminating Kit, Skin: M291
Device Description:	The RSDL lotion is pre-impregnated in a 2 x 3.9 x 0.4 inch, or 3.9 x 3.9 x 0.4 inch foam sponge applicator pad. Each applicator pad is packaged as a single unit in a heat-sealed polyethylene-lined aluminum foil pouch. The foil pouch is covered by a kraft paper outer layer to facilitate coloring of the finished package and to make opening the package possible when wearing CW protective clothing.
Intended Use:	The Reactive Skin Decontamination Lotion is intended to remove or neutralize chemical warfare agents and T-2 toxin from the skin.

Discussion of tests and test results:	The RSDL was subjected to a number of biocompatibility and safety tests and from the results of those tests, it can be concluded the RSDL is safe for its intended use. The RSDL was also tested for efficacy in removing and/or neutralizing groups of chemical warfare agents and T-2 toxin. RSDL performed significantly better than the predicate device against the agents tested. In tests evaluating the compatibility of RSDL with other agents military personnel would apply to the skin, RSDL was demonstrated to be compatible with all agents tested.
Conclusion:	This device, with respect to material composition, device characteristics and intended use, has been demonstrated to be safe and effective as a skin decontaminant, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2003

Department of the Army
C/O Mr. Ronald E. Clawson
Department of Defense
Chemical-Biological Mgt. Office
64 Thomas Johnson Drive
Fort Detrick, Maryland 21702

Re: K023969
Trade/Device Name: Reactive Skin Decontamination Lotion
Regulatory Class: II
Product Code: MAC
Dated: November 26, 2002
Received: November 29, 2002

Dear Mr. Clawson:

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.

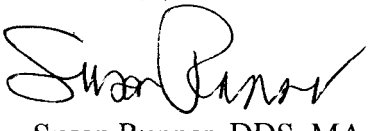
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023969

Device Name: Reactive Skin Decontamination Lotion

Indications for Use:

The Reactive Skin Decontamination Lotion is intended to remove or neutralize chemical warfare agents and T-2 toxin from the skin.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	OR	Over-The-Counter Use X

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K023969