JUN 19 2006

Premarket Notification Summary

K053409

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1. Sponsor Information:

3M Consumer Health Care
3M Center; 275-5W-06
St. Paul, MN 55144-1000

Contact Person: Bryan Becker
Senior Regulatory Affairs Associate
3M Health Care

Telephone Number: 651-733-3373
Fax Number: 651-737-5320

2. Device Name

Common or Usual Name: Liquid Bandage

Proprietary Name: 3M™ Liquid Bandage

Classification Name: Liquid Bandage (21 CFR §880.5090)

3. Predicate Device

Curad® Spray Bandage was selected as the predicate device for 3M™Liquid Bandage.

4. Description of Device

3M™ Liquid Bandage is a sterile, clear, liquid that covers minor cuts and scrapes that are clean and dry. The device is packaged in an aluminum tube with a reusable cap, a bottle with spray pump, or an individually wrapped swab.

5. Indications for Use

3M™ Liquid Bandage is indicated for use as an over-the-counter (OTC) device for consumer use to cover minor cuts and scrapes that are clean and dry.

6. Description of Safety and Substantial Equivalence

Technological Characteristics

The liquid bandage is applied to the wound to form a mechanical barrier. This thin film acts as a protective covering allowing the wound to heal. During wound healing, the polymer coating sloughs off naturally, as dead skin cells are shed and replaced with new cells.

Safety

An In-Vitro Cytotoxicity Test was completed on 3M™ Liquid Bandage to determine the cytotoxicity of the product. The test result was a reactivity grade of 1. In this test the liquid bandage was considered safe for its use.

A Human Repeat Insult Patch Test (HRIPT) was conducted to evaluate 3M™ Liquid Bandage for the induction of contact sensitization. No evidence of induced delayed contact hypersensitivity was observed.

A Human Cumulative Irritation Patch Test (HCIPT) was performed to evaluate 3M™ Liquid Bandage for the induction of cumulative irritation. The study concluded that the 3M™ Liquid Bandage is a mild material with essentially no evidence of experimental irritation.

Substantial Equivalence

3M™ Liquid Bandage is similar to Curad® Spray Bandage, in that both are organic polymer liquid bandages. They provide the same function, are for over-the-counter (OTC) consumer use, have similar claims, and they have the same indications for use. The two products are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2006

3M Company
% Mr. Bryan Becker
Senior Regulatory Affairs Associate
3M Center, Building 275-05-W-06
St. Paul, Minnesota 55144-1000

Re: K053409
Trade/Device Name: 3M™ Liquid Bandage
Regulatory Number: 21 CFR 880.5090
Regulatory Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: May 17, 2006
Received: May 23, 2006

Dear Mr. Becker:

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,

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

Indications for Use Statement

510(k) Number (if known): K053409

Device Name: 3M™ Liquid Bandage

Indications for Use:

3M™ Liquid Bandage is intended to cover minor cuts, scrapes, and skin irritations that are clean and dry.

Prescription Use____ OR Over-The-Counter-Use X

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K053409