DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Anna E. McRight
Product Regulation Manager
3M Health Care
3M Center, Bldg. 275-5W-06
St. Paul, Minnesota 55144-1000

OCT 2 1 2003

Re: K031263
Trade/Device Name: 3M™ Liquid Bandage
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid Bandage
Regulatory Class: I
Product Code: KMF
Dated: July 9, 2003
Received: July 10, 2003

Dear Ms. McRight:

This letter corrects our substantially equivalent letter of October 7, 2003, regarding the Indications for Use Statement.

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 (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 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.

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

Enclosure

Indications for Use Statement

510(k) Number (if known): K031263

Device Name: 3M™ Liquid Bandage

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter-Use _X__

Miriam C. Provost

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

510(k) Number K031263

K031263

OCT - 7 2003

Premarket Notification Summary

1. Sponsor Information:

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

Contact Person: Anna E. McRight
Product Regulation Manager
3M Health Care

Telephone Number: 651-733-7948
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)

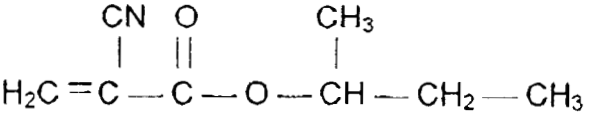
3. Predicate Device

Johnson & Johnson BAND-AID®[1] Liquid Bandage was selected as the predicate device for 3M™Liquid Bandage.

4. Description of Device

3M™ Liquid Bandage is a sterile, clear, n-2-butyl cyanoacrylate liquid used to cover minor cuts, scrapes, and minor skin irritations. The device is packaged in an aluminum tube with a reusable cap.

Chemical name: n-2-butyl cyanoacrylate
CAS registry number: 6606-65-1
Molecular formula: $C_8H_{11}NO_2$
Molecular weight (g/mole): 153
Structural formula:



[1] BAND-AID® is a registered trademark of Johnson & Johnson

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, scrapes, and skin irritations.

6. Description of Safety and Substantial Equivalence

Technological Characteristics:

The liquid bandage is applied to the wound and polymerizes to forms a mechanical bond with the skin, typically within one minute. This thin film acts as a 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 not performed because irritation was adequately tested in the induction phase of the HRIPT. The material was mildly to moderately irritating in a small number of the subjects.

Substantial Equivalence:

3M™ Liquid Bandage is similar to Johnson & Johnson BAND-AID® Liquid Bandage, in that both are cyanoacrylate liquid bandages. They provide the same function and are for over-the-counter (OTC) consumer use. The 3M™ Liquid Bandage is n-2-butyl cyanoacrylate, whereas Johnson & Johnson BAND-AID® Liquid Bandage is 2-octyl cyanoacrylate. The two products are substantially equivalent.