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K062602

5. 510(k) Summary or 510(k) Statement

510(k) Summary

DEC 1 1 2006

Submitted by:

Johnson & Johnson Consumer & Personal Products Company Worldwide, Division of Johnson & Johnson Consumer Companies, Inc.
199 Grandview Road
Skillman, NJ 08558

Contact Person:

Michelle R. Turk
Associate Director, Regulatory Affairs
Phone: (908) 904-3723
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Date of Summary Preparation:

August 21, 2006

Proprietary Name:

Johnson and Johnson Liquid Bandage

Classification (Common) Name:

Liquid Bandage

Device Classification:

21 CFR 880.5090
Regulation Name: Liquid Bandage
Regulatory Class: Class I
Product Code: KMF

Marketed Device(s) to which Equivalency is Claimed:

CURAD® Spray Bandage, K022645
Johnson and Johnson LIQUIDERM™ BAND-AID® Brand Liquid Bandage, K002338

Description of Device:

Solvent based liquid bandages are single- use liquid bandages that have three components: polymer solution, a foam applicator and aluminum foil pouch. Inside pouch, the swab is vertically situated with foam head down and saturated by the polymer solution. The pouch is sealed prior to use. The pouch will be open by tearing the notch. Upon

	application, the solvents will quickly evaporate and the polymer will form a clear and flexible film to cover skin /wound. The pouches will be sterilized either in bulk or in retail carton.
Intended Use:	The intended use of the BAND-AID® brand solvent based Liquid bandage is for providing a covering over minor cuts and scrapes that are clean and dry.
Technological Characteristic:	The liquid bandage is applied to the wound to form a protective barrier. The thin film is clear, flexible, breathable, and waterproof and acts as a protective covering allowing the wound to heal. The film remains on skin for several days, and naturally wears off as wound heals.
Evaluation of Substantial Equivalence:	Just as the Curad product, the BAND-AID® brand solvent based Liquid bandage is in liquid form prior to use. Both are a polymeric film formed upon solvent evaporation, have a film that is clear, flexible, breathable, and waterproof, and the film will remain on skin for several days, and naturally wears off as wound heals. If desired, they both can be removed by rubbing alcohol. The materials for the BAND-AID® brand solvent based Liquid bandage is biocompatible Per ISO 10993 Cytotoxicity, Sensitization, Irritation/Intracutaneous Reactivity, Systemic Toxicity, and Genotoxicity. Additionally, a Bovine Corneal Opacity and Permeability Assay study was conducted to assess potential eye irritancy. A Scarification study on humans to assess irritation potential was performed. Both the new and predicate and BAND-AID® Liquid bandage were categorized as being very low for irritation potential.
Conclusions	The proposed new Johnson and Johnson Liquid Bandage is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Johnson & Johnson Consumer Companies
% Ms. Michelle R. Turke
Associate Director, Regulatory Affairs
199 Grandview Road
Skillman, New Jersey 08858

DEC 1 1 2006

Re: K062602
Trade/Device Name: Johnson & Johnson Liquid Bandage
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: November 13, 2006
Received: November 14, 2006

Dear Ms. Turke:

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,

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

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): Unknown K062602

Device Name: Johnson & Johnson Liquid Bandage

Indications for Use: The intended use of the BAND-AID® brand solvent based Liquid bandage is for providing a covering over minor cuts and scrapes that are clean and dry

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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