NOV 5 2002

510(k) Summary for CURAD® Spray Bandage

K02 2645

1. SPONSOR

Beiersdorf AG
Hamburg, Germany
Contact Person: Mr. Volker Holle

2. Device Name

Proprietary Name: CURAD®
Common/Usual Name: Spray bandage
Classification Information:

Liquid bandages have been classified as Class I devices under the following classification name:

Name	Product Code	21 CFR Ref.	Panel
Liquid bandage	KMF	880.5090	General & Plastic Surgery

3. PREDICATE DEVICES

Liquiderm™ liquid adhesive bandage, 510(k) No. K002338.

4. DEVICE DESCRIPTION

The product is packaged in a pressurized can. The can is held about 5 inches from affected area, and a light coat is sprayed onto the skin. CURAD® Spray Bandage typically dries in 2-3 minutes. Once dried, additional coats can be applied, if needed.

CURAD® Spray Bandage will typically adhere for several days before losing its adhesive strength. To remove it before it has lost its adhesive strength, the user can apply isopropyl alcohol to the bandage to dissolve it.

CURAD® Spray Bandage is composed of the following ingredients:

poly(methylacrylate-isobutene-monoisopropylmaleate), ethyl acetate, n-pentane, carbon dioxide, menthol

The monomers of poly(methylacrylate-isobutene-monoisopropylmaleate) combine randomly with each other without preference.

5. INTENDED USE

CURAD® Spray Bandage is indicated for providing a covering over minor cuts and scrapes that are clean and dry.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

CURAD® Spray Bandage and Liquiderm™ liquid adhesive bandage have slightly different indication statements, but the intended use of the products—covering minor openings in the skin—are the same. Both products use a liquid polymer to cover the wound and have many of the same functional characteristics, such as water-tightness, water vapor permeability and flexibility.

7. PERFORMANCE TESTING

CURAD® Spray Bandage is flexible, transparent, and water-tight, but allows the passage of water vapor. In addition, CURAD® Spray Bandage seals out germs. A summary of testing to support each of these claims has been established and verified. A biocompatibility assessment was performed on the patient-contact materials of CURAD® Spray Bandage with satisfactory results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 5 2002

Beiersdorf AG
c/o Daniel J. Dillon
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K022645
Trade/Device Name: CURAD® Spray Bandage
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid Bandage
Regulatory Class: Class I
Product Code: KMF
Dated: August 7, 2002
Received: August 8, 2002

Dear Mr. Dillon:

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 and additionally 21 CFR 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Miriam C. Provost

for 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

510(k) Number (if known): K022645

Device Name: CURAD® Spray Bandage

Indications For Use:

CURAD® Spray Bandage is indicated for providing a covering over minor cuts and scrapes that are clean and dry.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, [illegible]orative
and Neurological De[illegible]ces

510(k) Number K022645

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

(Optional Format 1-2-96)