K032462

510(k) Summary for
CURAD® Silver Active Gel Bandage

1. SPONSOR

Beiersdorf AG
Hamburg, Germany

Contact Person: Mr. Volker Holle

Date Prepared: May 7, 2004

2. Device Name

Proprietary Name: CURAD® Silver Active Gel Bandage
Common/Usual Name: Occlusive wound dressings with added drug
Classification Information:

Occlusive wound dressings with added drugs have not yet been classified by the FDA or given a Product Code. Occlusive wound dressings without added drugs have been designated as Class I devices and exempt from 510(k) submission requirements. Other types of wound dressings with added drugs have been given a product code but not classified and several of the predicate products have been classified under the Product Code, "FRO." See below.

Names of Related Products	Product Code	21 CFR Ref.	Panel
Occlusive Wound Dressing	NAD	878.4020	General/Plastic Surgery
Hydrogel Wound and Burn Dressing with a Drug and/or Biologic	MGQ	None	General/Plastic Surgery
Nonabsorbable Gauze, Surgical Sponge, and Wound Dressing for External Use (with a Drug)	MXI	None	General/Plastic Surgery
Dressing	FRO	None	General/Plastic Surgery

3. PREDICATE DEVICES

CURAD® Silver Active Gel Bandage is substantially equivalent to the following devices:

Product	Submitter	510(k)
Silver Strips™ Adhesive Strips	Argentum Medical	K023609
Actisorb™ Silver 220 Antibacterial Binding Dressing	J & J Medical	K022483
Acticoat™ Composite Wound Dressing	Westaim Biomedical	K002466 & K983833
Aquacel® Ag with Hydrofiber Silver Impregnated Antimicrobi Dressing	ConvaTec	K013814

4. DEVICE DESCRIPTION

The CURAD® Silver Active Gel Bandage is a polyurethane occlusive bandage that includes silver oxide in the polyurethane matrix. The polyurethane provides a moist healing environment. At the same time, silver ions reduce bacterial growth in the wound pad.

5. INTENDED USE

The CURAD® Silver Active Gel Bandage is indicated for first aid to help in minor abrasions, cuts, lacerations, scrapes, and scalds.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

CURAD® Silver Active Gel Bandage has similar materials to other wound dressings with silver and equivalent concentrations of silver are released. A biocompatibility assessment was performed on the patient-contacting and fluid-path materials of CURAD® Silver Active Gel Bandage with satisfactory results.

7. PERFORMANCE TESTING

CURAD® Silver Active Gel Bandage was tested for silver release and antimicrobial effect and was demonstrated to have acceptable results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2004

Beiersdorf AG
c/o Mr. Daniel Dillon
Medial Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K032462
Trade/Device Name: CURAD® Silver Gel Bandage
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 14, 2003
Received: November 17, 2003

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), please contact the Office of Compliance at (301) 594-4659. 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,

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

510(k) Number (if known): K032462

Device Name: CURAD® Silver Gel Bandage

Indications for Use:

The CURAD® Silver Gel Bandage is indicated for first aid to help in minor abrasions, cuts, lacerations, scrapes, and scalds.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Restorative
Devices

K032462