

510(k) Summary

**Kendall Hydrophilic Powder Wound Dressing**

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Kendall Healthcare Products Company  
15 Hampshire Street  
Mansfield, MA 02048  
Date Prepared: April 21, 1997

1 Contact Person

David A. Olson  
Manager Regulatory Affairs  
(508) 261-8530

2 Name of Medical Device

Classification Name: **Unclassified**  
Common or Usual Name: **Hydrophilic Powder Wound Dressing**

3 Identification of Legally Marketed Device

The proposed Kendall Hydrophilic Powder Wound Dressing is substantially equivalent in intended use and composition to the commercially available DeRoyal Multidex® Hydrophilic Powder Wound Dressing, 510(k) No. K945000.

4 Device Description

The proposed Kendall Hydrophilic Powder Wound Dressing is a sterile composition of maltodextrin, sodium alginate and chitosan chloride. As the powder absorbs wound exudate it converts to a gel. This gel forms a moist environment at the wound interface conducive to healing. The product is available in 6 gram, 12 gram and 25 gram packets.

5 Device Intended Use

Like the predicate device, the Kendall Hydrophilic Powder Wound Dressing is indicated for the management of exuding wounds such as dermal ulcers (e.g., venous stasis, pressure, arterial, diabetic), surgical incisions, traumatic wounds (e.g., lacerations, abrasions).

K970266

6. Product Comparison

The Kendall Hydrophilic Powder Wound Dressing is equivalent to the referenced predicate device in that they are fabricated from similar materials, have a similar function and equivalent indications for use

7. Nonclinical Testing

Biocompatibility testing of the Kendall Hydrophilic Powder Wound Dressing has demonstrated that it contains no bioactive components. Testing performed on the product was based upon guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 19 2007

Mr. David A. Olson  
Manager, Regulatory Affairs  
Kendall Healthcare Products Company  
15 Hampshire Street  
Mansfield, Massachusetts 02048

Re: K970266  
Kendall Hydrophilic Powder Wound Dressing  
Regulatory Class: Unclassified  
Product Code: KGN  
Dated: January 22, 1997  
Received: January 23, 1997

Dear Mr. Williams:

This letter corrects our substantially equivalent letter of April 23, 1997.

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 and the following limitations:

1. This device may not be labeled for use on third degree burns.
2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81).

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.

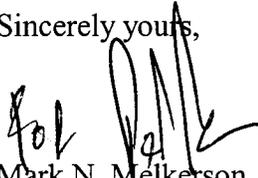
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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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/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

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