

510(k) Summary

Kendall Xeroform Petrolatum Wound Dressing

In accordance with section 513(l) 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: September 3, 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: Xeroform Petrolatum Wound Dressing

3. Identification of Legally Marketed Device

The proposed Kendall Xeroform Petrolatum Wound Dressing is substantially equivalent in intended use and composition to the Sherwood Medical Xeroform Petrolatum Dressing which was in commercial distribution before May 28, 1976.

4. Device Description

The proposed Kendall Xeroform Petrolatum Wound Dressing is a sterile, single-use, non-adherent dressing consisting of absorbent gauze impregnated with Xeroform in a petrolatum blend. It is packaged in metalized chevron pouches and is available in 4" x 3yd roll, 1" x 8", 5" x 9", 2" x 2" and 4" x 4" sizes.

5. Device Intended Use

The Kendall Xeroform Petrolatum Wound Dressing is intended for use as a primary contact layer in dressing wounds such as lacerations, skin graft recipient sites, newly sutured wounds, abrasions, and minor or partial thickness burns. It may also be used as an initial layer in dressing surgical wounds with light exudate where mild medication and deodorization are desired.

6. Product Comparison

The Kendall Xeroform Petrolatum 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 Xeroform Petrolatum 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

DEC 15 1997

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

Re: K973507
Kendall Xeroform Petrolatum Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: September 15, 1997
Received: September 16, 1997

Dear Mr. Olson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) 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). The general controls provisions of the Act include requirements for annual

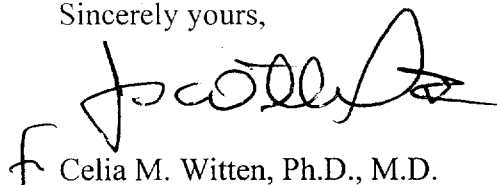
registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597 or at its internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

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

Director

Division of General and

Restorative Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K973507

510(k) Number (if known):

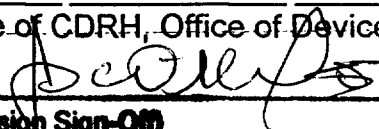
Device Name: Kendall Xeroform Petrolatum Dressing

Indications For Use:

It is intended for use as a primary contact layer in dressing wounds such as lacerations, skin graft recipient sites, newly sutured wounds, abrasions, and minor or partial thickness burns. It may also be used as an initial layer in dressing surgical wounds with light exudate where mild medication and deodorization are desired.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

K973507

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)