JAN 31 2000

EXHIBIT #12

K990530

510(k) Summary

Kendall Kerlix MD Antimicrobial Gauze 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:

The Kendall Company LP
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: February 12, 1999

1. Contact Person

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

2. Name of Medical Device

Classification Name: Unclassified
Common or Usual Name: Kerlix MD Antimicrobial Gauze Dressing

3. Identification of Legally Marketed Device

The proposed Kendall Kerlix MD Antimicrobial Gauze Dressing is substantially equivalent in intended use, function and composition to Vitaphore Corporations Vitapatch, 510(k) No. K895993 and Maersk Medical Ltd. Arglaes Antimicrobial Barrier Film Dressing, 510(k) No. K973657.

4. Device Description

The proposed Kerlix MD Antimicrobial Gauze Dressing is a sterile, single use, wound dressing consisting of gauze treated with Polyhexamethylene Biguanide Hydrochloride. The dressing is packaged in Tyvek/Poly pouches as well as Tyvek/Styrene trays and is available in both sponge and roll form.

5. Device Intended Use

The Kendall Kerlix MD Antimicrobial Gauze Dressing is intended for use as a primary dressing for exuding wounds, first and second degree burns, as a cover for surgical wounds, to secure and prevent movement of primary dressings and as a wound packing.

6. Product Comparison

The Kendall Kerlix MD Antimicrobial Gauze Dressing is equivalent to the referenced predicate devices in that they are intended to be used as wound coverings, they each contain an ingredient that enhances the bacterial barrier function of the dressing and each has a broad spectrum of antimicrobial activity.

7. Nonclinical Testing

Biocompatibility testing of the Kendall Kerlix MD Antimicrobial Gauze Dressing has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2000

Mr. Frank J. Fucile, Esq.
Vice President, Regulatory Affairs
The Kendall Company, L.P.
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K990530
Trade Name: Kendall Kerlix™ Antimicrobial Gauze
Regulatory Class: I
Product Code: NAD
Dated: October 11, 1999
Received: November 3, 1999

Dear Mr. Fucile:

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).

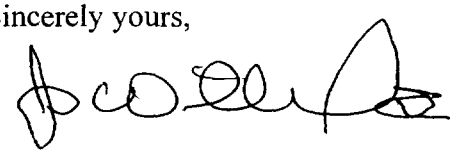
The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K990530

INDICATIONS FOR USE STATEMENT

510K Number: K990530

Device Name: Kendall **KERLIX™** Antimicrobial Gauze

Indications for Use:

KERLIX Antimicrobial Gauze is intended for use as a primary dressing for exuding wounds, first and second degree burns, and surgical wounds, to secure and prevent movement of a primary dressing, and as a wound packing

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____
(per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990530