K973509

Exhibit 9

DEC - 4 1997

510(k) Summary

In accordance with section 513(i)(3) of the SMDA and as described 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: September 4, 1997

1. Contact Person

Jan L. Efflandt, Regulatory Affairs
Telephone: (508) 261-8037

2. Name of Device

Classification Name:	Unclassified
Common or Usual Name:	Calcium Zinc and Magnesium Alginate Dressing
Proprietary Name:	CURASORB® Zn+Mg Alginate Wound Dressing

3. Statement of Substantial Equivalence

The Kendall CURASORB® Zn+Mg Alginate Wound Dressing is substantially equivalent in composition, form, function and intended use to the commercially available Kendall CURASORB® Calcium Alginate Dressing and Kendall CURASORB® Zn Alginate Wound Dressing.

4. Device Description

The Kendall CURASORB® Zn+Mg Alginate Wound Dressings are sterile, single-use, nonwoven, absorptive dressings. The off-white alginate fibers are composed of calcium, sodium, zinc and magnesium. As the dressing absorbs wound exudate it converts to a firm gel/fiber mat. This gel cushions the wound and forms a moist environment at the wound interface. The product is available in 2" x 2", 4" x 4", and 4" x 8", 6" x 10", 12" x 24" pads, as well as 12", 24" and 36" long wound packing rope.

5. Device Intended Use

Like predicate devices, the Kendall CURASORB® Zn+Mg Alginate Wound Dressings are external wound dressings designed to help protect the wound, provide a moist environment for wound healing, and absorb wound exudate. CURASORB® Zn+Mg Dressings are indicated for use on wounds which present moderate to heavy wound exudate

such as dermal ulcers, traumatic wounds, donor sites and second-degree burns.

6. Product Comparison

The Kendall CURASORB® Zn+Mg Alginate Wound Dressings are equivalent to the referenced predicate devices 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 CURASORB® Zn+Mg Alginate 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 I, 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

DEC - 4 1997

Ms. Jan L. Efflandt
Regulatory Affairs Administrator
Kendall Healthcare Products Company
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K973509
Kendall CURASORB® Zn+Mg Alginate Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: September 15, 1997
Received: September 16, 1997

Dear Ms. Efflandt:

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,

for 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

510(k) Number (if known): K973509

Device Name: CURASORB Zn+Mg Alginate Wound Dressing

Indications For Use:

The proposed device is for use in the management of wounds which present moderate to heavy wound exudate such as dermal ulcers (i.e., venous stasis, pressure, arterial, diabetic); traumatic wounds (i.e., lacerations, punctures, abrasions or incisions); donor sites; and second-degree burns.

(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 K973509

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

(Optional Format 1-2-96)