K973763

EXHIBIT #6

510(k) Summary

DEC 31 1997

Kendall Curity Iodoform Packing Strip

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: September 24, 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: Iodoform Packing Strip

3. Identification of Legally Marketed Device

The proposed Kendall Curity Iodoform Packing Strip is substantially equivalent in intended use and composition to the Johnson & Johnson Medical, Inc., NU Gauze® Iodoform Packing Strip which was in commercial distribution before May 28, 1976.

4. Device Description

The proposed Kendall Curity Iodoform Packing Strip is a sterile, single-use, wound dressing consisting of a cotton gauze strip impregnated with a formulated Iodoform solution. It is packaged in HDPE amber colored bottles and is available in ¼" x 5yd, ½" x 5yd, 1" x 5yd and 2" x 5yd sizes.

5. Device Intended Use

The Kendall Curity Iodoform Packing Strip is intended for wet to dry packing of deep wounds including nasal and sinus passages. It helps control/prevent bleeding, encourages drainage and assists in removing necrotic tissue.

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6. Product Comparison

The Kendall Curity Iodoform Packing Strip 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 Curity Iodoform Packing Strip 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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

DEC 31 1997

Re: K973763
Kendall Curity Iodoform Packing Strip
Regulatory Class: Unclassified
Product Code: EFQ
Dated: October 1, 1997
Received: October 2, 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,

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): K973763

Device Name: KENDALL CURITY IODOFORM PACKING STRIP

Indications For Use:

It is indicated for general wound packing.

(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 K973763

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

(Optional Format 1-2-96)