3/1/99

K984597

Summary of Safety and Effectiveness for
Cutinova® cavity - K984597

This 510(k) is being submitted for a modification to Cutinova cavity that was originally cleared for sale in the U.S. in 1995 (K952526)

Cutinova cavity is a polyurethane dressing that is indicated for the management of deep secondary healing wounds. The current modification involves a change in the material used to make the urethane from an aromatic diisocyanate to an aliphatic diisocyanate and does not affect the indications for use.

Biological tests were done in accordance with ISO 10993 and showed no negative effects for the modified Cutinova cavity. Performance characteristics were also comparable to the currently marketed product. In addition, a very small amount of α-Tocopherol was added to improve the thermal stability of the product.

Based on safety information in international data bases, biological testing and performance characteristics, it can be concluded that the modified Cutinova cavity is substantially equivalent to the current legally marketed Cutinova cavity.

Dated: February 9, 1999

Prepared by: Angelo Pereira
Manager, Regulatory Affairs
Beiersdorf-Jobst Inc.
5825 Carnegie Boulevard
Charlotte, N.C. 28209

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2007

Mr. Angelo Pereira
Beiersdorf-Jobst, Inc.
5825 Carnegie Boulevard
Charlotte, North Carolina 28209-4633

Re: K984597
Trade Name: Cutinova Cavity Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 23, 1998
Received: December 28, 1998

Dear Mr. Pereira:

This letter corrects our substantially equivalent letter of March 1, 1999.

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 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 including 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).

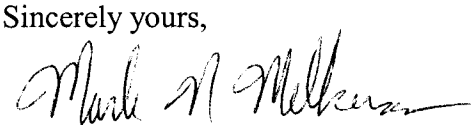
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

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,



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

K984597

510(k) Number (if known):_____

Device name: **Cutinova cavity**

Indications For Use:

Cutinova cavity is indicated for the management of deep secondary healing wounds such as:

Cavity wounds
Stage III and IV pressure ulcers
Deep leg ulcers
Excisions
Post-op wound dehiscence

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over The Counter Use_____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984597

K984597

510(k) Number K984597

Device name: **Cutinova cavity**

Indications For Use: Over-the-Counter

Cutinova cavity may be used under the direction of a health care professional for the management of deep secondary healing wounds such as:

Cavity wounds
Stage III and IV pressure ulcers
Deep leg ulcers
Excisions
Post-op wound dehiscence

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____
(Per 21 CFR 801.109)

OR Over The Counter Use X

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K984597