K970453

APR 11 1997

Attachment I

510(k) Summary
Transorbent and ThinSite Topical Border Wound Dressing

1. Submitted By: Brady Medical Products Co.
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Date Prepared: November 14, 1994

2. Name of Device: Transorbent Topical Border Wound Dressing
ThinSite Topical Border Wound Dressing
Common/Usual Name: Wound Dressing
Classification Name: Dressing, Wound and Burn, Hydrogel

3. Identification of predicate or legally marketed device or devices to which substantial equivalence claimed:

a) Transorbent Wound Dressing
Brady Medical Products

b) ThinSite (Transorb Thin) Wound Dressing
Brady Medical Products

c) B. F. Goodrich Biofilm
Transorbent Ulcer and Wound Dressing
B. F. Goodrich

d) Tegasorb™ THIN Hydrocolloid Dressing
3M Health Care

e) Tegasorb™ Ulcer Dressing
3M Health Care

f) Tegaderm™ HP Transparent Dressing
3M Health Care

g) Duoderm Flexible Hydroactive Dressing
Convatec, Squibb Co.

h) Duoderm Hydroactive Dressing and CGF Dressing
Convatec, Bristol-Myers Squibb Co.

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i) Duoderm CGF Border Dressings
Convatec, Bristol-Myers Squibb Co.

j) Duoderm CGF Extra Thin
Convatec, Bristol-Myers Squibb Co.

k) Nu-Derm Foam Island Dressings
Johnson and Johnson Medical, Inc.

l) Band-Aid Brand Surgical Dressings
Johnson and Johnson Medical, Inc.

4. Description of Device: The Transorbent and ThinSite Topical Border Wound Dressings are a multi-layered construction. The dressings utilize these various layers to optimize their functional abilities. The outer border film with adhesive bonds the dressing to the contact skin, and maintains the dressing in position until removed. Then there is an adhesive/fabric laminate that bonds the dressing to the wound site. The next layer is a hydrogel layer which absorbs and transfers exudate away from the wound, and captures it to facilitate the transfer of moisture vapor away from the wound. An integral adhesive bonds this portion of the dressing to an outer film (ThinSite) or film/foam (Transorbent) layer, which prevents excess loss of moisture at the wound site, while assisting in the transmission of moisture vapor from the dressing.

5. Intended use of the Device: The Transorbent and ThinSite Topical Border Wound Dressings are intended for use in the management of partial and full thickness wounds, Stage I - IV pressure ulcers, arterial and venous stasis leg ulcers, and to aid in the prevention of skin breakdown. They are also intended for use in post-surgical wounds, biopsy sites, minor abrasions and lacerations, suture sites, partial thickness and full thickness dermatological sites, laparoscopic incisional sites, and drainage tube sites.

6. The technological characteristics of this device are comparable to the aforementioned devices, in that they are all composite devices which employ a laminar construction. All employ a skin adhesive to provide anchorage to the dressing site. Further, the Transorbent and ThinSite Topical Border Wound Dressings have undergone biocompatibility testing, which Brady Medical Products knows is comparable to the B. F. Goodrich, Transorbent, and ThinSite products. This extensive testing has in all probability been undergone by the other indicated products.