

SEP 23 1996

K963039

**510(k) SUMMARY**  
**SureSkin™ Hydrocolloid Wound Dressings**  
**Labeling Revision**

**1. DATE PREPARED**

August 2, 1996

**2. SUBMITTER**

Euromed A/S  
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**3. CONTACT**

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**4. DEVICE NAME**

SureSkin™ STANDARD Hydrocolloid Wound Dressing  
SureSkin™ BORDER Hydrocolloid Wound Dressing  
SureSkin™ THIN Hydrocolloid Wound Dressing

**5. DEVICE CLASSIFICATION**

Wound Dressings have not been finally classified by FDA.  
[Proposed Class I (21 CFR 878.4022)]  
Product Code: 79 MGP

**6. DEVICE DESCRIPTION AND COMPARISON TO PREDICATE PRODUCTS**

The SureSkin™ Hydrocolloid Wound Dressings manufactured by Euromed A/S are indicated for the management of dry and exudating pressure sores and leg ulcers. The devices were originally cleared for marketing under K960393--SureSkin™ BORDER Dressing, K960394--SureSkin™ STANDARD Dressing, and K960404--SureSkin™ THIN Dressing. The only purpose of the current 510(k) premarket notification for these products is to update the device labeling to be consistent with equivalent products. The three dressings will be contraindicated for use on 3rd degree burns. No other changes have been made to the devices since the original marketing clearance was obtained and therefore, no other specific performance or biocompatibility testing was included in this submission.