

K961452

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MAY 31 1996



Acme United Corporation

## 510(K) SUMMARY

Submitter's Name: Acme United Corporation  
 75 Kings Highway Cutoff  
 Fairfield, CT 06430

Contact Person: Thomas E. Flynn, Director of Regulatory  
 Affairs and Quality Assurance

Telephone Number: 203-332-7330

Fax Number: 203-576-0007

Date of Submission:

"This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMMA 1990 and 21 CFR 807.92."

The assigned 510(K) number is:

Proprietary Name of Device: Lyofoam® Extra "A" Sterile Adhesive  
 Wound Dressing

Common/Usual Name: Extra absorbent, polyurethane foam  
 island dressing.

Classification Name: Dressing, Class I

Product Claiming  
 Equivalence To: Modified Lyofoam® Wound Dressing and  
 Lyofoam® Extra Absorbent Wound  
 Dressing

Description of Device: Lyofoam® Extra "A", Extra Absorbent,  
 Non-Adherent Polyurethane Foam  
 Dressing with adhesive boarder.

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Intended Use, Comparison To  
Predicate Device:

The Lyofoam® Extra "A" Sterile Adhesive Wound Dressing is a combination of the Lyofoam® Extra product and the Modified Lyofoam® Dressing Product (Lyofoam® "A"). The main difference between them is that Lyofoam® Extra Foam Dressing is used in place of the regular Lyofoam® for the wound dressing pad segment of this product. The third layer of thin foam is extended beyond the wound pad and has a adhesive coating which is used to hold the product in place over the wound.

The inner absorbent layer of Lyofoam® Extra Wound Dressing Pad holds more excess wound fluid than the Modified Lyofoam® Wound Dressing Pad which is made from regular Lyofoam®. The Lyofoam® Extra "A" Sterile Adhesive Wound Dressing is intended for the treatment of moderately to heavily exuding wounds while the Modified Lyofoam® Wound Dressing would be used to treat lightly to moderately exuding, wounds. Lyofoam® Extra "A" provides a waterproof barrier for the wound which is moisture vapor permeable and helps to prevent bacterial contamination of the wound.

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Performance data for this product can be found in the Lyofoam® Extra 510(K) File K952565.

Safety:

Safety test data can be found in both the Lyofoam® Extra 510(K) file K952565 and Modified Lyofoam® Dressing file; K895764. All safety data is summarized in those files and indicates product is safe for use.

Sterility and Packaging:

Lyofoam® Extra "A" Sterile Adhesive Wound Dressing is packaged in a paper/foil peel pouch and is sterilized using gamma radiation and has a SAL  $10^{-6}$ .