

K970693

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Summary of Safety and Effectiveness

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Device Name (proprietary): AcryDerm Gel Wound Dressing

Common Name: Moist wound dressing

Classification Name: Hydrogel wound dressing

Classification: Unclassified; as recommended by the General and Plastic Surgery Devices Panel 79

Legally marketed device(s) for substantial equivalence comparison:

AcryDerm Advanced Wound Dressing, (AcryMed, Inc.)
IntraSite Gel, (Smith & Nephew Medical Ltd.)
Carrasyn Hydrogel Wound Dressing, (Carrington Laboratories, Inc.)

Description of Device: AcryDerm Gel Wound Dressing is a clear amorphous hydrogel moist wound dressing for external use. AcryDerm Gel will be supplied in the following sizes: 1/2-oz squeeze tube; 1-oz squeeze tube; and 3-oz squeeze tube. AcryDerm Gel will be supplied sterile (gamma radiation), in individual primary squeeze tubes packaged with Instructions for Use into an intermediate labeled box and distributed in various case sizes. Biocompatibility has been established according to Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*).

Intended Use of the Device: AcryDerm Gel is an external wound dressing that is designed as a moisture donating substrate for use in promoting natural autolytic debridement by rehydrating necrotic tissues. AcryDerm Gel is indicated for use as an external wound dressing in the management of chronic wounds such as pressure sores, diabetic ulcers, radiation dermatitis, peristomal skin irritations, and stasis ulcers, and acute wounds such as surgical wounds, lacerations, donor site, first and second degree burns, and abrasions. AcryDerm Gel may be used on infected wounds under medical supervision. AcryDerm Gel is not intended as a long duration dressing for the treatment of third degree burns.

Technological Characteristics: AcryDerm Gel is composed of a modified synthetic polyacrylate polymer, glycerol, carboxymethyl cellulose ionic buffering salts, polysaccharide, preservatives and water. It is an amorphous gel that carries the same general classification name, "Hydrogel", as do AcryDerm Advanced Wound Dressing, Intrasite Gel and Carrasyn Hydrogel Wound Dressing. The classification, intended uses, composition, and methods of manufacturing of AcryDerm Gel wound Dressing are substantially equivalent to the predicate devices.

Performance Characteristics: AcryDerm Gel is an amorphous gel that is designed to provide intimate contact with the wound or irritated tissues and to donate moisture to tissues surrounding the application site. Laboratory tests have shown that AcryDerm Gel releases moisture to absorbent substrates.

Manufacturing: AcryDerm Gel will be manufactured according to the product specifications and under good manufacturing practices that ensure the device is safe and effective for its intended use.