K961319

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ITEM 8: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

The purpose of this 510(k) Premarket Notification is to request clearance to market EpiVIEW Thin Film Dressing.

EpiVIEW Thin Film Dressing is indicated as a securement device and dressing for peripheral and central IV catheters. It may be used as a wound dressing on minor abrasions, superficial pressure ulcers, over eschar to facilitate debridement, skin graft donor sites, closed clean surgical wounds and first and second degree burns. EpiVIEW may also be used to prevent skin breakdown from chafing or from exposure to continuous moisture and friction .

EpiVIEW Thin Film Dressing is not intended for use over infected catheter sites or infected wounds, or over arterial sites. The dressing is not intended to replace sutures.

EpiVIEW Thin Film Dressing is substantially equivalent to 3M's Tegaderm Transparent Dressing, K811291. Both devices have essentially the same intended uses, contraindications, precautions and observations. EpiVIEW Thin Film Dressing is similar in construction and design to Tegaderm; both dressings consist of a thin polyurethane film coated with an acrylic adhesive wound contact layer.

Both dressings have been tested and have been shown to have the same peel adhesion (N/cm), moisture vapor transmission rate, and elasticity. The EpiVIEW dressing compared with Tegaderm is shown to have a lower coefficient of friction (COF) value, which would mean a lower incidence of shearing during human wear. Results for moisture vapor transmission rate show both dressings have substantially equivalent MVTR profiles. In addition, both dressings showed no significant differences in elasticity.

EpiVIEW Thin Film Dressing has been subjected to biocompatibility testing utilizing the ISO 10993 Part I "Biological Evaluation of Medical Devices" with FDA modified matrix (Guidance effective July 1, 1995). The results of this testing demonstrate that EpiVIEW is considered to be non-toxic, non-cytotoxic, non-hemolytic, a negligible irritant and having a weak allergenic potential. Test reports appear in Item 5 of this application.