

K780853 OP-SITE ADHESIVE DRAPESAug 14, 1978
84 days to decisionK780853 · Product code: **KKX** · General Hospital
Source: <https://www.510kdatabase.net/k780853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drape, Surgical (KKX)
Date received	May 22, 1978
Decision date	Aug 14, 1978
Days to decision	84 days
Third-party review	No

APPLICANT

Company	Acme United Corp.
Location	Mchenry, IL, US
510(k) history	27 submissions · 23 cleared · 1976-1996

Acme United Corp. is an American manufacturer of cutting, measuring, and safety products headquartered in McHenry, US. The company has operated globally since its incorporation in 1873. Acme United has submitted FDA 510(k) applications and received clearances between 1976 and 1996. The company's regulatory focus centered on General & Plastic Surgery devices, which comprised 78% of submissions. Notable cleared products include wound dressings, surgical sheets, and enteral feeding systems. This company is inactive and represents a historical regulatory record only. Explore ...