

**K861015 ONE TIME HYPERAL & CATHETER DRESSING
CHANGE TRAYS**Apr 22, 1986
35 days to decisionK861015 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k861015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Mar 18, 1986
Decision date	Apr 22, 1986
Days to decision	35 days
Third-party review	No

APPLICANT

Company	Acme United Corp.
Location	Mchenry, IL, US
Contact	SUSAN L CAREY
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 ...
