

K864084 LYOFOAM C ODOR-ABSORBING DRESSINGNov 21, 1986
32 days to decisionK864084 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k864084/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------|
| Decision | Substantially Equivalent - SN |
| Submission type | Traditional |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Oct 20, 1986 |
| Decision date | Nov 21, 1986 |
| Days to decision | 32 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 ...
