FDA 510(k) Premarket Notification

K843781 KINAIR, LOW AIR LOSS BED

CLEARED

Jan 28, 1985
124 days to decision

K843781 · Product code: **FNL** · General Hospital
Source: https://www.510kdatabase.net/k843781/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bed, Ac-powered Adjustable Hospital (FNL)
Date received	Sep 26, 1984
Decision date	Jan 28, 1985
Days to decision	124 days
Third-party review	No

APPLICANT

Company	**Kinetic Concepts, Inc.**
Location	Mchenry, IL, US
Contact	ROBERT A WEHRMEYER
Website	http://www.kci-medical.com
510(k) history	48 submissions · 48 cleared · 1978-2005

Kinetic Concepts, Inc. was a global medical technology corporation specializing in wound care and negative pressure wound therapy solutions. Headquartered in San Antonio, Texas, the company developed foundational technologies for wound healing and operated in more than 25 countries. The company received FDA 510(k) clearances from total submissions between 1978 and 2005. Its regulatory portfolio focused primarily on General & Plastic Surgery devices, with notable clearances in wound closure and negative pressure therapy systems. This represents a strong historical track re...

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Device record: https://www.510kdatabase.net/k843781/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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