

K955243 BARIAIROct 23, 1997
708 days to decisionK955243 · Product code: **FNM** · General Hospital
Source: <https://www.510kdatabase.net/k955243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mattress, Air Flotation, Alternating Pressure (FNM)
Date received	Nov 15, 1995
Decision date	Oct 23, 1997
Days to decision	708 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kinetic Concepts, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM H QUIRK
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...
