FDA 510(k) Premarket Notification

K954320 MODIFIED PEDIKAIR

CLEARED

Jul 18, 1997
680 days to decision

K954320 · Product code: **FNM** · General Hospital
Source: https://www.510kdatabase.net/k954320/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mattress, Air Flotation, Alternating Pressure (FNM)
Date received	Sep 7, 1995
Decision date	Jul 18, 1997
Days to decision	680 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...

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