FDA 510(k) Premarket Notification

K921768 HAZEL II

CLEARED

Apr 29, 1992
15 days to decision

K921768 · Product code: **IOQ** · Physical Medicine
Source: https://www.510kdatabase.net/k921768/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bed, Flotation Therapy, Powered (IOQ)
Date received	Apr 14, 1992
Decision date	Apr 29, 1992
Days to decision	15 days
Third-party review	No
Summary / Statement	Statement

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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