FDA 510(k) Premarket Notification

K905390 KUDO (POWERED ROTATION BED)

CLEARED

Jan 8, 1991
39 days to decision

K905390 · Product code: **IKZ** · Physical Medicine
Source: https://www.510kdatabase.net/k905390/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bed, Patient Rotation, Powered (IKZ)
Date received	Nov 30, 1990
Decision date	Jan 8, 1991
Days to decision	39 days
Third-party review	No

APPLICANT

Company	**Kinetic Concepts, Inc.**
Location	Mchenry, IL, US
Contact	WEHRMEYER, JR
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k905390/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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