

K891151 COOL &N HEAT MACHINEApr 6, 1989
34 days to decisionK891151 · Product code: **ILO** · Physical Medicine
Source: <https://www.510kdatabase.net/k891151/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Water Circulating (ILO)
Date received	Mar 3, 1989
Decision date	Apr 6, 1989
Days to decision	34 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...

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