FDA 510(k) Premarket Notification

K912537 JACE MODEL K200 KNEE CPM DEVICE, MODIFICATION

CLEARED

Aug 16, 1991
67 days to decision

K912537 · Product code: **BXB** · Physical Medicine
Source: https://www.510kdatabase.net/k912537/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Exerciser, Powered (BXB)
Date received	Jun 10, 1991
Decision date	Aug 16, 1991
Days to decision	67 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Thera Kinetics, Inc.**
Location	Mt. Laurel, NJ, US
Contact	MARK KOZAK
510(k) history	3 submissions · 3 cleared · 1990-1991