FDA 510(k) Premarket Notification

K961176 OMNI COLD GEL PACKS

CLEARED

Sep 4, 1996
163 days to decision

K961176 · Product code: **IMD** · Physical Medicine
Source: https://www.510kdatabase.net/k961176/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pack, Hot Or Cold, Disposable (IMD)
Date received	Mar 25, 1996
Decision date	Sep 4, 1996
Days to decision	163 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Omni Therm, Inc.**
Location	St. Louis, MO, US
Contact	MATT WALTERS
510(k) history	5 submissions · 4 cleared · 1987-1996

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k961176/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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