FDA 510(k) Premarket Notification

K091615 MED CONTOUR

CLEARED

May 6, 2010
337 days to decision

K091615 · Product code: **IMI** · Physical Medicine
Source: https://www.510kdatabase.net/k091615/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat (IMI)
Date received	Jun 3, 2009
Decision date	May 6, 2010
Days to decision	337 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**General Project S.R.L.**
Location	North Reading, MA, US
Contact	MAUREEN O'CONNELL
510(k) history	5 submissions · 5 cleared · 2005-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k091615/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026