

K160608 NormaTec Pulse and NormaTec Pulse ProApr 13, 2016
41 days to decisionK160608 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k160608/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Mar 3, 2016
Decision date	Apr 13, 2016
Days to decision	41 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	NormaTec Industries, LP
Location	Washington, DC, US
Contact	Peter Novello
510(k) history	9 submissions · 9 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160608/> 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 May 26, 2026