

K183702 Polar Care WaveMar 1, 2019
60 days to decisionK183702 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k183702/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Dec 31, 2018
Decision date	Mar 1, 2019
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Breg, Inc.
Location	Costa Mesa, CA, US
Contact	Monique Zamora
510(k) history	16 submissions · 16 cleared · 1991-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183702/> 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 28, 2026