FDA 510(k) Premarket Notification

CLEARED

K211283 Compressible Limb and Circulation Therapy System, Model POWER-Q2300

Sep 14, 2021
140 days to decision

K211283 · Product code: **IRP** · Physical Medicine
Source: https://www.510kdatabase.net/k211283/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Apr 27, 2021
Decision date	Sep 14, 2021
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Wonjin Mulsan Co., Ltd.**
Location	La Mirada, CA, US
Contact	Ha Yong Jung
510(k) history	5 submissions · 5 cleared · 2009-2021

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k211283/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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