FDA 510(k) Premarket Notification

K231437 LF900

CLEARED

Jul 19, 2023
63 days to decision

K231437 · Product code: **IRP** · Physical Medicine
Source: https://www.510kdatabase.net/k231437/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	May 17, 2023
Decision date	Jul 19, 2023
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Daesung Maref Co., Ltd.**
Location	Buena Park, CA, US
Contact	Su Hyeon So
510(k) history	14 submissions · 14 cleared · 2011-2023