

K203498 LX9maxJul 2, 2021
217 days to decisionK203498 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k203498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Nov 27, 2020
Decision date	Jul 2, 2021
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203498/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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