

K202395 SP-1000, SP-2000Sep 1, 2021
376 days to decisionK202395 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k202395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Aug 21, 2020
Decision date	Sep 1, 2021
Days to decision	376 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Daesung Maref Co., Ltd.
Location	Buena Park, CA, US
Contact	Hyoung Ju Cho
510(k) history	14 submissions · 14 cleared · 2011-2023

REGULATORY CONSULTANT

Consulting firm	Global Medical Standard Consulting Co., Ltd.
Contact	Do Gyun Lim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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