

K191441 Air Relax, Compressible Limb Sleeve System (Model: AR-1.0, AR-2.0)Mar 5, 2021
645 days to decisionK191441 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k191441/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	May 30, 2019
Decision date	Mar 5, 2021
Days to decision	645 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Maxstar Industrial Co., Ltd.
Location	Los Angeles, CA, US
Contact	Jonghwa Lim
510(k) history	3 submissions · 3 cleared · 2014-2021

REGULATORY CONSULTANT

Consulting firm	Med.Com
Contact	Chris Park

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191441/> 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 May 27, 2026