

K212491 Air Relax Pro Model AR-4.0Sep 2, 2021
24 days to decisionK212491 · Product code: **IRP** · Physical Medicine
Source: <https://www.510kdatabase.net/k212491/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Powered Inflatable Tube (IRP)
Date received	Aug 9, 2021
Decision date	Sep 2, 2021
Days to decision	24 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Diode Art Engineering Doing Business AS Air Relax
Location	Pico Rivera, CA, US
Contact	Beomjoon Lee
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212491/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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