

K252273 Therapy US

Dec 12, 2025
143 days to decision

K252273 · Product code: **NHN** · Physical Medicine
Source: <https://www.510kdatabase.net/k252273/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Laser Non-thermal Instrument With Non-heating Effect For Adjunctive Use In Pain Therapy (NHN)
Date received	Jul 22, 2025
Decision date	Dec 12, 2025
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dmc Importa??o E Exporta??o DE Equipamentos Ltda
Location	S?o Carlos, BR
Contact	Renaldo Massini Junior
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Pr Servi?os Regulat?rios Administrativos Ltda
Contact	Tatiana Jabor Botura

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