

K232813 Therapy EC, Therapy XTDec 19, 2024
463 days to decisionK232813 · Product code: **NHN** · Physical Medicine
Source: <https://www.510kdatabase.net/k232813/>**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	Sep 13, 2023
Decision date	Dec 19, 2024
Days to decision	463 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dmc Importacao E Exportacao DE Equipamentos Ltda
Location	Sao Carlos, BR
Contact	Renata Beninca Pereira
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Pr Servicos Regulatorios Administrativos Ltda
Contact	Homero Santiago Antunes

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/k232813/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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