FDA 510(k) Premarket Notification

K192749 Dermadry

CLEARED

Feb 10, 2020
133 days to decision

K192749 · Product code: **EGJ** · Physical Medicine
Source: https://www.510kdatabase.net/k192749/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Iontophoresis, Other Uses (EGJ)
Date received	Sep 30, 2019
Decision date	Feb 10, 2020
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dermadry Laboratories, Inc.**
Location	Montreal, CA
Contact	Maxime Calouche
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Lok North America, Inc.**
Contact	Louis-Paul Marin

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