FDA 510(k) Premarket Notification

K212155 TheraFace LED

CLEARED

Dec 21, 2021
162 days to decision

K212155 · Product code: **OHS** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212155/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Jul 12, 2021
Decision date	Dec 21, 2021
Days to decision	162 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Theragun, Inc.**
Location	Los Angeles, CA, US
Contact	Jaime Sanchez
510(k) history	3 submissions · 3 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Schiff & Company, Inc.**
Contact	Thomas Padula

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