

**K212155 TheraFace LED**Dec 21, 2021  
162 days to decisionK212155 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212155/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Schiff &amp; Company, Inc.</b>
Contact	Thomas Padula

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212155/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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