

**K222081 ID-510 iRestore Elite**Oct 13, 2022  
90 days to decisionK222081 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222081/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Jul 15, 2022
Decision date	Oct 13, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Freedom Laser Therapy, Inc.</b>
Location	Los Angeles, CA, US
Contact	Wei-Chih Chen
510(k) history	4 submissions · 4 cleared · 2016-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Emergo Global Consulting, LLC</b>
Contact	Sharon Chen

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

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