

K213094 ID-500 iRestore Hair Growth SystemDec 22, 2021
89 days to decisionK213094 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Sep 24, 2021
Decision date	Dec 22, 2021
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
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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