

K211192 Grivamax Family of Lasers, Models 272 and 148Jul 20, 2021
90 days to decisionK211192 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211192/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Apr 21, 2021
Decision date	Jul 20, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Leana Orders, Inc.
Location	Staten Island, NY, US
Contact	Leonid Krits
510(k) history	2 submissions · 2 cleared · 2017-2021

REGULATORY CONSULTANT

Consulting firm	Nst Consultants, Inc.
Contact	Raymond R. Blanche

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211192/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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