

**K221268 SR-1 Skin Treatment System**Nov 21, 2022  
203 days to decisionK221268 · Product code: **ONG** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221268/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument With Microbeamfractional Output (ONG)
Date received	May 2, 2022
Decision date	Nov 21, 2022
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Avava, Inc.</b>
Location	Waltham, MA, US
Contact	Jay Bhawalkar
510(k) history	6 submissions · 6 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221268/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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