

**K233550 MOSAIC 3D (Surgical Laser)**Jan 2, 2024  
60 days to decisionK233550 · Product code: **ONG** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k233550/>**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	Nov 3, 2023
Decision date	Jan 2, 2024
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lutronic Aesthetic</b>
Location	Billerica, MA, US
Contact	Sarah Dunne
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233550/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026