

**K250195 MateLaser Medical Laser Therapy Systems (ML-HIL-30, ML-HIL-60)**May 30, 2025  
127 days to decisionK250195 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250195/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 23, 2025
Decision date	May 30, 2025
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Matelaser, Inc.</b>
Location	Miami, FL, US
Contact	Ruth Garcia
510(k) history	2 submissions · 2 cleared · 2025-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250195/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026