

**K192331 LaseMD LEO Laser System**Nov 12, 2019  
77 days to decisionK192331 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192331/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 27, 2019
Decision date	Nov 12, 2019
Days to decision	77 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Lutronic Global</b>
Location	Billerica, MA, US
Contact	James Childs
510(k) history	1 submissions · 1 cleared · 2019-2019

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192331/> 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 June 29, 2026