

**K990043 SMOOTHLASE ALEXANDRITE LASER SYSTEM**Feb 11, 1999  
36 days to decisionK990043 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k990043/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 6, 1999
Decision date	Feb 11, 1999
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Leisegang Medical, Inc.</b>
Location	Miami, FL, US
Contact	LORNA K LINVILLE
510(k) history	10 submissions · 10 cleared · 1986-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k990043/> 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