

**K091320 SPECTRA SP II, SPECTRA DENTA II**Aug 19, 2009  
106 days to decisionK091320 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k091320/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 5, 2009
Decision date	Aug 19, 2009
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lutronic Corporation</b>
Location	North Reading, MA, US
Contact	MAUREEN O'CONNELL
510(k) history	29 submissions · 29 cleared · 2007-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091320/> 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 22, 2026