

**K163196 ACTION II Laser System**May 24, 2017  
190 days to decisionK163196 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163196/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 15, 2016
Decision date	May 24, 2017
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lutronic Corporation</b>
Location	North Reading, MA, US
Contact	Jhung Won Vojir
510(k) history	29 submissions · 29 cleared · 2007-2025

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