

K152032 ELUMI 810 + 980 Soft Tissue LaserSep 16, 2015
56 days to decisionK152032 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k152032/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 22, 2015
Decision date	Sep 16, 2015
Days to decision	56 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Azena Medical, LLC
Location	Walnut Creek, CA, US
Contact	ALEX DI SESSA
510(k) history	4 submissions · 4 cleared · 2015-2026

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