

K192617 Gemini 810+980 Soft Tissue LaserFeb 20, 2020
150 days to decisionK192617 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k192617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 23, 2019
Decision date	Feb 20, 2020
Days to decision	150 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192617/> Data sourced from FDA 510(k) public records (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. - Generated May 21, 2026