

**K233007 Picosecond Nd:YAG Laser System**Jun 12, 2024  
264 days to decisionK233007 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233007/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 22, 2023
Decision date	Jun 12, 2024
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	PICO LEGEND

**APPLICANT**

---

Company	<b>Ami, Inc.</b>
Location	Seoul, KR
Contact	Hae Lee Youn
510(k) history	3 submissions · 3 cleared · 2017-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Braunsolutions Regulatory Group</b>
Contact	Alexander Braun Henderson

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233007/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026