

K242035 Accure Laser SystemOct 11, 2024
91 days to decisionK242035 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242035/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 12, 2024
Decision date	Oct 11, 2024
Days to decision	91 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Accure Acne, Inc.
Location	Boulder, CO, US
Contact	Alfred Intintoli
510(k) history	2 submissions · 2 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	FDA Compliance Group
Contact	Kevin Walls

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.netDevice record: <https://www.510kdatabase.net/k242035/> 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 13, 2026