

K222109 Accure LaserNov 17, 2022
122 days to decisionK222109 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 18, 2022
Decision date	Nov 17, 2022
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Accure Acne, Inc.
Location	Boulder, CO, US
Contact	Karl Nicholls
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)

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