FDA 510(k) Premarket Notification

K222109 Accure Laser

CLEARED

Nov 17, 2022
122 days to decision

K222109 · Product code: **GEX** · General & Plastic Surgery
Source: 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