FDA 510(k) Premarket Notification

K242035 Accure Laser System

CLEARED

Oct 11, 2024
91 days to decision

K242035 · Product code: **GEX** · General & Plastic Surgery
Source: 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