FDA 510(k) Premarket Notification

K213461 AviClear Laser System

CLEARED

Mar 24, 2022
148 days to decision

K213461 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213461/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 27, 2021
Decision date	Mar 24, 2022
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cutera, Inc.**
Location	Brisbane, CA, US
Contact	Amogh Kothare
Website	http://www.cutera.com/
510(k) history	31 submissions · 31 cleared · 2004-2025

Cutera, Inc. is a medical device manufacturer specializing in aesthetic and surgical laser systems. The company operates with a manufacturing facility in Brisbane, US, and maintains a global presence across North America, Europe, and Australia. Cutera has established a strong regulatory track record with the FDA. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2004. The vast majority of its submissions focus on General & Plastic Surgery devices, reflecting the company's core expertise in this category. The most recent cle...