FDA 510(k) Premarket Notification

K182997 enlighten III Laser System

CLEARED

Dec 12, 2018
43 days to decision

K182997 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k182997/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 30, 2018
Decision date	Dec 12, 2018
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cutera, Inc.**
Location	Brisbane, CA, US
Contact	Julia Brown
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...