

K233237 xeo+ FamilyDec 15, 2023
78 days to decisionK233237 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 28, 2023
Decision date	Dec 15, 2023
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cutera, Inc.
Location	Brisbane, CA, US
Contact	Irina Glazkova
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...