

**K133945 CUTERA PICOSECOND LASER SYSTEM**Aug 11, 2014  
231 days to decisionK133945 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k133945/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 23, 2013
Decision date	Aug 11, 2014
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cutera, Inc.</b>
Location	Brisbane, CA, US
Contact	BRADLEY RENTON
Website	<a href="http://www.cutera.com/">http://www.cutera.com/</a>
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...

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