

K050047 CUTERA OPTIONAL PULSED LIGHT HAND PIECE FAMILYMar 31, 2005
80 days to decisionK050047 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k050047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 10, 2005
Decision date	Mar 31, 2005
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cutera, Inc.
Location	Brisbane, CA, US
Contact	KATHY MAYNOR
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...