

K042165 CUTERA TABLETOP AESTHETIC PRODUCTOct 18, 2004
68 days to decisionK042165 · Product code: **ILY** · Physical MedicineSource: <https://www.510kdatabase.net/k042165/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lamp, Infrared, Therapeutic Heating (ILY)
Date received	Aug 11, 2004
Decision date	Oct 18, 2004
Days to decision	68 days
Third-party review	Yes
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...
