FDA 510(k) Premarket Notification

CLEARED

K080530 MODIFICATION TO CUTERA ER:YSGG LASER HANDPIECE

Aug 15, 2008
171 days to decision

K080530 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k080530/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 26, 2008
Decision date	Aug 15, 2008
Days to decision	171 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...