FDA 510(k) Premarket Notification

CLEARED

K103626 CUTERA GENESISPLUS LASER SYSTEM

Apr 5, 2011
116 days to decision

K103626 · Product code: **PDZ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k103626/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lasers For Temporary Increase Of Clear Nail In Patients With Onychomycosis (PDZ)
Date received	Dec 10, 2010
Decision date	Apr 5, 2011
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cutera, Inc.**
Location	Brisbane, CA, US
Contact	Connie Hoy
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...