FDA 510(k) Premarket Notification

K123777 MULTILASER SYSTEM

CLEARED

Apr 11, 2013
122 days to decision

K123777 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k123777/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 10, 2012
Decision date	Apr 11, 2013
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ultralight Laser Technologies, LLC**
Location	Birmingham, AL, US
Contact	MARK ROHRER
510(k) history	1 submissions · 1 cleared · 2013-2013