FDA 510(k) Premarket Notification

K033183 RECLEAR PHOTOTHERAPY SYSTEM, MODEL FGCM0012

CLEARED

Apr 15, 2004
197 days to decision

K033183 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k033183/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 1, 2003
Decision date	Apr 15, 2004
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Curelight, Ltd.**
Location	Washington, DC, US
Contact	JONATHAN S KAHAN
510(k) history	6 submissions · 6 cleared · 2002-2004