FDA 510(k) Premarket Notification

K032191 OMNILIGHT FLUORESCENT PULSED LIGHT SYSTEM

CLEARED

Aug 20, 2003
34 days to decision

K032191 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k032191/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 17, 2003
Decision date	Aug 20, 2003
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Luxsano AB**
Location	Woodland, CA, US
Contact	Connie Hoy
510(k) history	1 submissions · 1 cleared · 2003-2003