FDA 510(k) Premarket Notification

K013748 CANDELA SCLERO LONG PULSE LASER (AKA VBEAM)

CLEARED

Feb 11, 2002
90 days to decision

K013748 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k013748/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 13, 2001
Decision date	Feb 11, 2002
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Candela Corp.**
Location	Natick, MA, US
Contact	L NELSON
510(k) history	48 submissions · 48 cleared · 1986-2019