FDA 510(k) Premarket Notification

K981351 CANDELA GENTLELASE GL DERMATOLOGICAL LASER

CLEARED

Jul 13, 1998
90 days to decision

K981351 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k981351/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 14, 1998
Decision date	Jul 13, 1998
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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