FDA 510(k) Premarket Notification

K994260 CANDELA GENTLELASE GL DERMATOLOGICAL LASER

CLEARED

May 26, 2000
161 days to decision

K994260 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k994260/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 17, 1999
Decision date	May 26, 2000
Days to decision	161 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k994260/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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