

K191685 PicoWay Laser SystemSep 16, 2019
84 days to decisionK191685 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k191685/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 24, 2019
Decision date	Sep 16, 2019
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Candela Corporation
Location	Wayland, MA, US
Contact	Brenda Geary
510(k) history	8 submissions · 8 cleared · 2015-2024

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