

K220853 PicoWay Laser SystemOct 13, 2022
204 days to decisionK220853 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 23, 2022
Decision date	Oct 13, 2022
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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