

K160607 PicoWay Laser SystemJul 5, 2016
125 days to decisionK160607 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k160607/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 2, 2016
Decision date	Jul 5, 2016
Days to decision	125 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Syneron Candela Corporation
Location	Wayland, MA, US
Contact	Ruthie Amir
510(k) history	5 submissions · 5 cleared · 2016-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160607/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026