FDA 510(k) Premarket Notification

K160607 PicoWay Laser System

CLEARED

Jul 5, 2016
125 days to decision

K160607 · 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