FDA 510(k) Premarket Notification

K162454 PicoWay Laser System

CLEARED

Feb 1, 2017
153 days to decision

K162454 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k162454/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 1, 2016
Decision date	Feb 1, 2017
Days to decision	153 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