FDA 510(k) Premarket Notification

K181523 Syneron CO2RE System

CLEARED

Jul 11, 2018
30 days to decision

K181523 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k181523/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 11, 2018
Decision date	Jul 11, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Syneron-Candela Corp**
Location	Wayland, MA, US
Contact	Sharon Timberlake
510(k) history	1 submissions · 1 cleared · 2018-2018