FDA 510(k) Premarket Notification

K161043 Profound System

CLEARED

Sep 12, 2016
152 days to decision

K161043 · Product code: **PBX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k161043/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Apr 13, 2016
Decision date	Sep 12, 2016
Days to decision	152 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