

**K161043 Profound System**Sep 12, 2016  
152 days to decisionK161043 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k161043/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161043/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026