

**K183452 Vbeam Prima Laser System**Feb 1, 2019  
50 days to decisionK183452 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k183452/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 13, 2018
Decision date	Feb 1, 2019
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Candela Corp.</b>
Location	Natick, MA, US
Contact	Sharon Timberlake
510(k) history	48 submissions · 48 cleared · 1986-2019

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183452/> Data sourced from FDA 510(k) public records (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. - Generated June 18, 2026