

K133283 CANDELA GENTLEMAX FAMILY OF LASER SYSTEMSDec 26, 2013
62 days to decisionK133283 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k133283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 25, 2013
Decision date	Dec 26, 2013
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Candela Corp.
Location	Natick, MA, US
Contact	SAM WADE
510(k) history	48 submissions · 48 cleared · 1986-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133283/> 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