

K133895 DEKA SMARTXIDE LASER SYSTEMSep 5, 2014
259 days to decisionK133895 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k133895/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 20, 2013
Decision date	Sep 5, 2014
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	El.En S.P.A.
Location	Hopkinton, MA, US
Contact	GEORGE CHO
510(k) history	15 submissions · 15 cleared · 2014-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133895/> 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 May 25, 2026