

K131095 DEKA SYNCHRO REPLA: Y FAMILY OF LASER SYSTEMSDec 5, 2013
231 days to decisionK131095 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k131095/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 18, 2013
Decision date	Dec 5, 2013
Days to decision	231 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	EI.En Electronic Engineering Spa
Location	Calenzano, IT
Contact	PAOLO PERUZZI
510(k) history	27 submissions · 27 cleared · 2007-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131095/> 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 7, 2026