

K101904 SMARTXIDE 50 HS/MSJan 12, 2011
188 days to decisionK101904 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k101904/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 8, 2010
Decision date	Jan 12, 2011
Days to decision	188 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/k101904/> 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 20, 2026