

K162851 eLyx-PROJan 24, 2017
105 days to decisionK162851 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k162851/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 11, 2016
Decision date	Jan 24, 2017
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Intelligent Sensory Concept SA
Location	Senarclens, CH
Contact	Joel Chanteraud
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162851/> 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 1, 2026