

**K201594 Primelase Excellence**Dec 17, 2020  
188 days to decisionK201594 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k201594/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 12, 2020
Decision date	Dec 17, 2020
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>High Technology Products S.L.U</b>
Location	Barcelona, ES
Contact	Sergi Lozano
510(k) history	3 submissions · 3 cleared · 2019-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Freyr Global Regulatory Solutions &amp; Services</b>
Contact	Vardhini Kirthivas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201594/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 29, 2026