

**K253344 BELLUS-Q**Nov 25, 2025  
56 days to decisionK253344 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253344/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2025
Decision date	Nov 25, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Specclipse, Inc.</b>
Location	Gyeonggi-Do, KR
Contact	Myung Seo Park
510(k) history	2 submissions · 2 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253344/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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