

**K213557 Finexel**Apr 12, 2022  
155 days to decisionK213557 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213557/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 8, 2021
Decision date	Apr 12, 2022
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Snj Co., Ltd.</b>
Location	Seoul, KR
Contact	Taehi Chang
510(k) history	2 submissions · 2 cleared · 2021-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bio-Med USA, Inc.</b>
Contact	Chi Young

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/k213557/> 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 May 26, 2026