

**K222555 reepot Nd**Sep 23, 2022  
31 days to decisionK222555 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222555/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 23, 2022
Decision date	Sep 23, 2022
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	YAG laser system

**APPLICANT**

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Company	<b>Ilooda Co.,, Ltd.</b>
Location	Gwonseon-Gu, Suwon-Si, KR
Contact	Yunjung HA
510(k) history	16 submissions · 16 cleared · 2015-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Bt Solutions, Inc.</b>
Contact	Do Hyun Kim

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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222555/> 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