

**K160312 FRAXIS DUO**Oct 28, 2016  
266 days to decisionK160312 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k160312/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 5, 2016
Decision date	Oct 28, 2016
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160312/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026