

**K152611 V20 system**Feb 19, 2016  
158 days to decisionK152611 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k152611/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 14, 2015
Decision date	Feb 19, 2016
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Viora , Ltd.</b>
Location	Jersey City, NJ, US
Contact	OMRI KESLER
510(k) history	11 submissions · 11 cleared · 2009-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152611/> 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 June 22, 2026