

**K191962 Vitra 2**Dec 5, 2019  
135 days to decisionK191962 · Product code: **GEX** · Ophthalmic  
Source: <https://www.510kdatabase.net/k191962/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 23, 2019
Decision date	Dec 5, 2019
Days to decision	135 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quantel Medical</b>
Location	Cournon D&apos;Auvergne-Cedex, FR
Contact	Bruno Pages
Website	<a href="https://www.quantelmedical.com">https://www.quantelmedical.com</a>
510(k) history	30 submissions · 30 cleared · 2000-2026

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191962/> 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 14, 2026