

**K242132 FREDDO**Oct 18, 2024  
88 days to decisionK242132 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k242132/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 22, 2024
Decision date	Oct 18, 2024
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fabinject Industria E Comercio Lmportacao E Exportacao Ltda</b>
Location	Taubate, BR
Contact	Gianmaria Cominato Filho
510(k) history	1 submissions · 1 cleared · 2024-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242132/> 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 13, 2026