

**K153229 Superbium**Apr 12, 2016  
158 days to decisionK153229 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k153229/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 6, 2015
Decision date	Apr 12, 2016
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bios S.R.L.</b>
Location	Silver Spring, MD, US
Contact	Riccardo Pisati
510(k) history	14 submissions · 14 cleared · 2005-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153229/> 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