

**K043521 BIOSYAG 50 MED**Mar 24, 2005  
94 days to decisionK043521 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k043521/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 20, 2004
Decision date	Mar 24, 2005
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043521/> 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