

**K182270 Cellene CO2 Laser System**Nov 2, 2018  
72 days to decisionK182270 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182270/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 22, 2018
Decision date	Nov 2, 2018
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bio-Med USA, Inc.</b>
Location	Paterson, NJ, US
Contact	Young Chi
510(k) history	10 submissions · 10 cleared · 2008-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182270/> 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