

**K221789 IRIS Pi Q switched Nd YAG laser**Aug 9, 2022  
49 days to decisionK221789 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221789/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jun 21, 2022
Decision date	Aug 9, 2022
Days to decision	49 days
Third-party review	No
Combination product	No
PCCP authorized	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/k221789/> 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