

**K043319 CLAREON AND SOLARUS PULSED LIGHT DEVICES  
AND ACCESSORIES**Dec 17, 2004  
15 days to decisionK043319 · Product code: **GEX** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k043319/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 2, 2004
Decision date	Dec 17, 2004
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Novalis Medical, LLC</b>
Location	Tampa, FL, US
Contact	ANTHONY DAVIS
510(k) history	1 submissions · 1 cleared · 2004-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043319/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated July 3, 2026