

**K082028 LASERPEEL SOFT-MET MODIFIED ERBIUM LASER**Aug 8, 2008  
22 days to decisionK082028 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k082028/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 17, 2008
Decision date	Aug 8, 2008
Days to decision	22 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Global USA Distribution, LLC</b>
Location	Bloomington, MN, US
Contact	MATT MAKOUSKY
510(k) history	4 submissions · 4 cleared · 2008-2008

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082028/> 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 June 24, 2026