

**K220531 FOX 810, FOX 980**Sep 1, 2022  
189 days to decisionK220531 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k220531/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 24, 2022
Decision date	Sep 1, 2022
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>A.R.C Laser GmbH</b>
Location	Rockville, MD, US
Contact	Angela Thyzel
510(k) history	6 submissions · 6 cleared · 2008-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k220531/> 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