

**K053161 SIROLASER**Jan 18, 2006  
65 days to decisionK053161 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k053161/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Nov 14, 2005
Decision date	Jan 18, 2006
Days to decision	65 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sirona Dental Systems GmbH</b>
Location	N. Attleboro, MA, US
Contact	FRITZ KOLLE
510(k) history	42 submissions · 42 cleared · 1998-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k053161/> 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 16, 2026