

**K161004 Self-retaining Retractor**Sep 9, 2016  
151 days to decisionK161004 · Product code: **GZT** · Neurology  
Source: <https://www.510kdatabase.net/k161004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Retractor, Self-retaining, For Neurosurgery (GZT)
Date received	Apr 11, 2016
Decision date	Sep 9, 2016
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fetzer Medical GmbH &amp; Co. KG</b>
Location	Tuttlingen, DE
Contact	Harald Jung
510(k) history	3 submissions · 3 cleared · 2016-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161004/> 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 30, 2026