

**K163209 Fiagon Navigation System**Sep 14, 2017  
303 days to decisionK163209 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k163209/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Nov 15, 2016
Decision date	Sep 14, 2017
Days to decision	303 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fiagon GmbH</b>
Location	Hennigsdorf, DE
Contact	Dirk Mucha
510(k) history	15 submissions · 15 cleared · 2014-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163209/> 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