

**K152764 EXACTECH GPS**Jul 13, 2016  
293 days to decisionK152764 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k152764/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 24, 2015
Decision date	Jul 13, 2016
Days to decision	293 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Blue Ortho</b>
Location	La Tronche, FR
Contact	ANTHONY BOYER
510(k) history	9 submissions · 9 cleared · 2010-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k152764/> 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