

**K151359 ROSA Brain**Dec 18, 2015  
212 days to decisionK151359 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k151359/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	May 20, 2015
Decision date	Dec 18, 2015
Days to decision	212 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtech S.A</b>
Location	Montpellier, FR
Contact	MICHAEL CHRIST
510(k) history	8 submissions · 8 cleared · 2009-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151359/> 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 June 22, 2026