

**K214065 ROSA ONE Brain application**May 4, 2022  
128 days to decisionK214065 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k214065/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Dec 27, 2021
Decision date	May 4, 2022
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtech S.A.S</b>
Location	Montpellier, FR
Contact	Paul Hardy
510(k) history	3 submissions · 3 cleared · 2010-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k214065/> 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 27, 2026