

**K231103 ROSA ONE Brain Application**Jul 20, 2023  
92 days to decisionK231103 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k231103/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Apr 19, 2023
Decision date	Jul 20, 2023
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231103/> 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