

K182417 ROSA ONE Brain ApplicationFeb 7, 2019
155 days to decisionK182417 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k182417/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Sep 5, 2018
Decision date	Feb 7, 2019
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtech S.A
Location	Montpellier, FR
Contact	Serge Tabet
510(k) history	8 submissions · 8 cleared · 2009-2020

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