

K172444 ROSA BRAIN (v3.0.0.5)Mar 28, 2018
226 days to decisionK172444 · Product code: **HAW** · Neurology
Source: <https://www.510kdatabase.net/k172444/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Aug 14, 2017
Decision date	Mar 28, 2018
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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