FDA 510(k) Premarket Notification

K214065 ROSA ONE Brain application

CLEARED

May 4, 2022
128 days to decision

K214065 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k214065/

SUBMISSION DETAILS

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

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