

K213273 Brain Anesthesia Response Monitor (Bar Monitor)Sep 1, 2023
701 days to decisionK213273 · Product code: **OLW** · Anesthesiology
Source: <https://www.510kdatabase.net/k213273/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Sep 30, 2021
Decision date	Sep 1, 2023
Days to decision	701 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cortical Dynamics , Ltd.
Location	North Perth, AU
Contact	Louis Delacretaz
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Tim Marjenin

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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