

K222838 iSyncBrain©-CMar 16, 2023
177 days to decisionK222838 · Product code: **OLU** · Neurology
Source: <https://www.510kdatabase.net/k222838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Normalizing Quantitative Electroencephalograph Software (OLU)
Date received	Sep 20, 2022
Decision date	Mar 16, 2023
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	iMediSync, Inc.
Location	Seoul, KR
Contact	Young-Geun Kim
510(k) history	2 submissions · 2 cleared · 2022-2023

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