

K242094 Dreem 3SNov 22, 2024
128 days to decisionK242094 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k242094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Jul 17, 2024
Decision date	Nov 22, 2024
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Beacon Biosignals, Inc.
Location	Boston, MA, US
Contact	Alexander Chan
510(k) history	3 submissions · 3 cleared · 2023-2024

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