

K223539 Dreem 3SAug 18, 2023
268 days to decisionK223539 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k223539/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Nov 23, 2022
Decision date	Aug 18, 2023
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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