FDA 510(k) Premarket Notification

K233438 SleepStageML

CLEARED

Mar 8, 2024
147 days to decision

K233438 · Product code: **OLZ** · Neurology
Source: https://www.510kdatabase.net/k233438/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Oct 13, 2023
Decision date	Mar 8, 2024
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

APPLICANT

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