

K163617 REMbrandtApr 11, 2017
110 days to decisionK163617 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k163617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Dec 22, 2016
Decision date	Apr 11, 2017
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Embla Systems
Location	Thornton, CO, US
Contact	Shane T Sawall
510(k) history	8 submissions · 8 cleared · 2011-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163617/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026