

K153353 SANDMAN ELITEJun 23, 2016
216 days to decisionK153353 · Product code: **OLZ** · Neurology
Source: <https://www.510kdatabase.net/k153353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Nov 20, 2015
Decision date	Jun 23, 2016
Days to decision	216 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/k153353/> 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