FDA 510(k) Premarket Notification

K163617 REMbrandt

CLEARED

Apr 11, 2017
110 days to decision

K163617 · 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