

K201054 SOMNOscreen plusAug 12, 2020
113 days to decisionK201054 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k201054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Apr 21, 2020
Decision date	Aug 12, 2020
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Somnomedics GmbH
Location	Washington, DC, US
Contact	Stephanie Wolski
510(k) history	7 submissions · 7 cleared · 2007-2024

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