FDA 510(k) Premarket Notification

K223922 SOMNUM (V.1.1.2.)

CLEARED

Aug 16, 2023
229 days to decision

K223922 · Product code: **OLZ** · Neurology
Source: https://www.510kdatabase.net/k223922/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Polysomnograph With Electroencephalograph (OLZ)
Date received	Dec 30, 2022
Decision date	Aug 16, 2023
Days to decision	229 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Honeynaps Co., Ltd.**
Location	Seoul, KR
Contact	Tony Lee
510(k) history	1 submissions · 1 cleared · 2023-2023