FDA 510(k) Premarket Notification

K222680 DeltaScan Monitor

CLEARED

Feb 2, 2023
149 days to decision

K222680 · Product code: **NCG** · Neurology
Source: https://www.510kdatabase.net/k222680/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neuropsychiatric Interpretative Electroencephalograph Assessment Aid (NCG)
Date received	Sep 6, 2022
Decision date	Feb 2, 2023
Days to decision	149 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Prolira B.V.**
Location	Utrecht, NL
Contact	Rutger O. van Merkerk
510(k) history	2 submissions · 2 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Corolla Clin/Reg Consulting**
Contact	Paul J Manberg

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

CLINICAL EVIDENCE - NCT03966274

DeltaScan Validation Study for the Assessment of Delirium in the ICU and on Wards

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	434 patients (actual)
Study sites	1 site
Condition studied	Delirium
Study type	Observational
Completion date	Feb 12, 2021
Sponsor	UMC Utrecht (Other)

Primary outcome

The positive and negative predictive value of DeltaScan

Secondary outcome

Sensitivity and Specificity of DeltaScan

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03966274