

K202621 NeuroSENSE Monitoring System, Model NS-901Aug 5, 2021
329 days to decisionK202621 · Product code: **OLW** · Anesthesiology
Source: <https://www.510kdatabase.net/k202621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Sep 10, 2020
Decision date	Aug 5, 2021
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurowave Systems, Inc.
Location	Cleveland Heights, OH, US
Contact	Tatjana Zikov
510(k) history	3 submissions · 3 cleared · 2010-2021

CLINICAL EVIDENCE - NCT02088671

Effectiveness of the NeuroSENSE for Monitoring the Hypnotic Depth of Anesthesia

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	76 patients (actual)
Study sites	2 sites
Condition studied	Depth of Anesthesia (DOA)
Study type	Observational
Completion date	Oct 1, 2016
Sponsor	NeuroWave Systems Inc. (Industry)

Primary outcome

Prediction probability Pk for the WAVcns for consciousness vs unconsciousness

Secondary outcome

Prediction probability Pk for the WAVcns for responders vs nonresponders to lidocaine aerosol

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02088671