

K223615 Digital ClarusScope System, Digital NeuroPEN SystemNov 21, 2023
351 days to decisionK223615 · Product code: **GWG** · Neurology
Source: <https://www.510kdatabase.net/k223615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Neurological (GWG)
Date received	Dec 5, 2022
Decision date	Nov 21, 2023
Days to decision	351 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Clarus Medical, LLC
Location	Minneapolis, MN, US
Contact	Mark F. Brown
510(k) history	9 submissions · 9 cleared · 2001-2024

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