

K240575 WaveGuard Net EEG Cap (NA-245, NA-255, NA-261, NA-265, NA-271, NA-281)Nov 25, 2024
269 days to decisionK240575 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k240575/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Mar 1, 2024
Decision date	Nov 25, 2024
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eemagine Medical Imaging Solutions GmbH
Location	Mukwonago, WI, US
Contact	Maarten van de Velde
510(k) history	8 submissions · 8 cleared · 2000-2024

REGULATORY CONSULTANT

Consulting firm	Quality and Regulatory Help, LLC
Contact	Dana Coggin

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

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