

**K211315 Comby EEG Caps**Nov 9, 2021  
193 days to decisionK211315 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k211315/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Apr 30, 2021
Decision date	Nov 9, 2021
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pamel D.O.O</b>
Location	Zagreb, HR
Contact	Marko Pavic
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Be-On-Quality GmbH</b>
Contact	Stefan Bolleiningger

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211315/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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