

**K211643 Vision Monitor - MonpackONE**Jul 26, 2021  
60 days to decisionK211643 · Product code: **GWE** · Ophthalmic  
Source: <https://www.510kdatabase.net/k211643/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Photic, Evoked Response (GWE)
Date received	May 27, 2021
Decision date	Jul 26, 2021
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Metrovision</b>
Location	Perenchies, FR
Contact	Jacques Charlier
510(k) history	2 submissions · 2 cleared · 2021-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211643/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026