

**K212936 Vision Monitor- MonCvONE**Nov 21, 2022  
432 days to decisionK212936 · Product code: **GWE** · Ophthalmic  
Source: <https://www.510kdatabase.net/k212936/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Photic, Evoked Response (GWE)
Date received	Sep 15, 2021
Decision date	Nov 21, 2022
Days to decision	432 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/k212936/> 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