

**K254004 VRNT**Apr 10, 2026  
116 days to decisionK254004 · Product code: **QRA** · Physical Medicine  
Source: <https://www.510kdatabase.net/k254004/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Virtual Reality Behavioral Therapy Device For Pain Relief (QRA)
Date received	Dec 15, 2025
Decision date	Apr 10, 2026
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cognifisense, Inc.</b>
Location	Sunnyvale, CA, US
Contact	Amanda Way
510(k) history	2 submissions · 2 cleared · 2023-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254004/> 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 13, 2026