

**K242447 Falcon HST**Feb 20, 2025  
188 days to decisionK242447 · Product code: **OLV** · Neurology  
Source: <https://www.510kdatabase.net/k242447/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Aug 16, 2024
Decision date	Feb 20, 2025
Days to decision	188 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Compumedics Limited</b>
Location	Minneapolis,, MN, US
Contact	John Joseph
510(k) history	9 submissions · 9 cleared · 2000-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

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/k242447/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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