

**K011397 PERSYST REVEAL**Aug 3, 2001  
88 days to decisionK011397 · Product code: **OMB** · Neurology  
Source: <https://www.510kdatabase.net/k011397/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | Automatic Event Detection Software For Full-montage Electroencephalograph (OMB) |
| Date received         | May 7, 2001   |
| Decision date         | Aug 3, 2001   |
| Days to decision      | 88 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Persyst Development Corp.</b>      |
| Location       | Prescott, AZ, US                      |
| Contact        | SCOTT B WILSON                        |
| 510(k) history | 4 submissions · 4 cleared · 1998-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011397/> 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 June 8, 2026