

**K120516 LONG LIFE PADTM**May 17, 2012  
86 days to decisionK120516 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k120516/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Electrode, Cutaneous (GXY)         |
| Date received         | Feb 21, 2012                       |
| Decision date         | May 17, 2012                       |
| Days to decision      | 86 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Omron Healthcare, Inc.</b>           |
| Location       | Vernon Hills, IL, US                    |
| Contact        | PAUL DRYDEN                             |
| 510(k) history | 68 submissions · 67 cleared · 1991-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120516/> 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 14, 2026