

**K123358 PACIFIC PLUS**Jan 29, 2013  
90 days to decisionK123358 · Product code: **LIT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k123358/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                    |
| Submission type       | Traditional   |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received         | Oct 31, 2012  |
| Decision date         | Jan 29, 2013  |
| Days to decision      | 90 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Medtronic Vascular</b>                 |
| Location       | Walker, MI, US                            |
| Contact        | DIANA JOHNSON                             |
| 510(k) history | 475 submissions · 453 cleared · 1977-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123358/> 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 14, 2026