

**K041468 PREMICAL, 1261.205**Sep 9, 2004  
99 days to decisionK041468 · Product code: **LJS** · General Hospital  
Source: <https://www.510kdatabase.net/k041468/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Jun 2, 2004
Decision date	Sep 9, 2004
Days to decision	99 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Vygon Corp.</b>
Location	East Rutherford, NJ, US
Contact	COURTNEY SMITH
510(k) history	48 submissions · 46 cleared · 1985-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041468/> 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 26, 2026