

**K120160 ROCAMED ROCAUS PLATINUM**May 14, 2012  
116 days to decisionK120160 · Product code: **KNY** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k120160/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Catheter, G-u (KNY)
Date received	Jan 19, 2012
Decision date	May 14, 2012
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Promepla Sam</b>
Location	Monaco, MC
Contact	KRISTA JOHNSON
510(k) history	5 submissions · 5 cleared · 2012-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120160/> 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 26, 2026