

**K050112 PRO FIT DISPOSABLE RECTAL SPECULUM, MODELS  
8116 AND 8117**Mar 15, 2005  
56 days to decisionK050112 · Product code: **KPL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k050112/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonic Irrigation System (KPL)
Date received	Jan 18, 2005
Decision date	Mar 15, 2005
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Prime Pacific Health Innovations Corporation</b>
Location	North Vancouver, CA
Contact	DELMAR VOGEL
510(k) history	2 submissions · 2 cleared · 2001-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050112/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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