

**K140558 PROCTIGARD**Jul 16, 2014  
133 days to decisionK140558 · Product code: **PHN** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k140558/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Protective Coating, Mucoadhesive Application, For The Rectal Mucosa (PHN)
Date received	Mar 5, 2014
Decision date	Jul 16, 2014
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Access Pharmaceuticals, Inc.</b>
Location	Dallas, TX, US
Contact	JEFFREY B DAVIS
510(k) history	2 submissions · 2 cleared · 2006-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140558/> 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 6, 2026