

**K131852 HC-1 AND HC-1 CLASSIC**Apr 17, 2014  
300 days to decisionK131852 · Product code: **KPL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k131852/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonic Irrigation System (KPL)
Date received	Jun 21, 2013
Decision date	Apr 17, 2014
Days to decision	300 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Transcendencias Comerciales SL Transcom</b>
Location	San Sebastian, Guipuzcoa, ES
Contact	RAMON ECHEVARRIA
510(k) history	1 submissions · 1 cleared · 2014-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131852/> 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 7, 2026