

**K000388 CLEARWATER COLON HYDROTHERAPY  
(DISPOSABLE SPECULUM SPO1 LARGE & SPO2 SMALL)**Aug 8, 2000  
183 days to decisionK000388 · Product code: **KPL** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k000388/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colonic Irrigation System (KPL)
Date received	Feb 7, 2000
Decision date	Aug 8, 2000
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clearwater Colon Hydrotherapy, Inc.</b>
Location	Ocala, FL, US
Contact	STUART K BAKER
510(k) history	2 submissions · 2 cleared · 1996-2000

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000388/> 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 30, 2026