

**K913361 DRAIN/PRIMING/RECIRCULATION BAG**Mar 30, 1992  
245 days to decisionK913361 · Product code: **KOC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k913361/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Blood Circuit, Hemodialysis (KOC)
Date received	Jul 29, 1991
Decision date	Mar 30, 1992
Days to decision	245 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Haemotronic, Inc.</b>
Location	Fairfield, NJ, US
Contact	WILLER GHELFI
510(k) history	4 submissions · 4 cleared · 1992-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913361/> 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