

**K881218 GENT-L-KARE CLEANSING ENEMA SET**Jul 28, 1988  
128 days to decisionK881218 · Product code: **FCE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k881218/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enema Kit (FCE)
Date received	Mar 22, 1988
Decision date	Jul 28, 1988
Days to decision	128 days
Third-party review	No

**APPLICANT**

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Company	<b>Geneva Laboratories, Inc.</b>
Location	Walker, MI, US
Contact	GARY L SWANSON
510(k) history	13 submissions · 13 cleared · 1981-1988

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k881218/>; 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