

**K901182 ENEMA BAG SET**Jun 28, 1990  
107 days to decisionK901182 · Product code: **FCE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k901182/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Enema Kit (FCE)
Date received	Mar 13, 1990
Decision date	Jun 28, 1990
Days to decision	107 days
Third-party review	No

**APPLICANT**

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Company	<b>Orion Life Systems, Inc.</b>
Location	Wheeling, IL, US
Contact	JOHN L LAEMMAR
510(k) history	33 submissions · 16 cleared · 1990-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k901182/>; 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 May 26, 2026