

**K974042 AMSURE CLEANSING ENEMA SET**Dec 19, 1997  
56 days to decisionK974042 · Product code: **FCE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k974042/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enema Kit (FCE)
Date received	Oct 24, 1997
Decision date	Dec 19, 1997
Days to decision	56 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Amsino Intl., Inc.</b>
Location	City Of Industry, CA, US
Contact	RICHARD Y LI
510(k) history	9 submissions · 9 cleared · 1995-2007

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