

K082831 AMSELF CLOSED CATHETERIZATION SYSTEMOct 23, 2008
27 days to decisionK082831 · Product code: **FCM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k082831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tray, Catheterization, Sterile Urethral, With Or Without Catheter (kit) (FCM)
Date received	Sep 26, 2008
Decision date	Oct 23, 2008
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Amsino International, Inc.
Location	Ontario, CA, US
Contact	CHING CHING SEAH
510(k) history	27 submissions · 27 cleared · 2002-2022

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