

K101824 AMSURE 3-WAY HYDROPHILIC LATEX FOLEY CATHETERSep 13, 2010
74 days to decisionK101824 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k101824/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jul 1, 2010
Decision date	Sep 13, 2010
Days to decision	74 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k101824/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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