

K030120 AMSURE FOLEY CATHETEROct 29, 2003
289 days to decisionK030120 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k030120/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention Type, Balloon (EZL)
Date received	Jan 13, 2003
Decision date	Oct 29, 2003
Days to decision	289 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Amsino International, Inc.
Location	Ontario, CA, US
Contact	CHING CHING SEAH
510(k) history	28 submissions · 28 cleared · 2002-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030120/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026