FDA 510(k) Premarket Notification

K030120 AMSURE FOLEY CATHETER

CLEARED

Oct 29, 2003
289 days to decision

K030120 · 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