FDA 510(k) Premarket Notification

K101824 AMSURE 3-WAY HYDROPHILIC LATEX FOLEY CATHETER

CLEARED

Sep 13, 2010
74 days to decision

K101824 · 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