

K181445 AMSure Hydrophilic Intermittent CatheterOct 1, 2018
122 days to decisionK181445 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181445/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Jun 1, 2018
Decision date	Oct 1, 2018
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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