

**K112734 APLAN A.V. FISTULA NEEDLE SET**Apr 24, 2012  
217 days to decisionK112734 · Product code: **FIE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k112734/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Sep 20, 2011
Decision date	Apr 24, 2012
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aplan Well Enterprise Co., Ltd.</b>
Location	Hsin Chu City, TW
Contact	JEN KE-MIN
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112734/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 14, 2026