

**K171505 Dimesol Disposable AV Fistula Needle Set (Non-Safety Series) and Dimesol Disposable AV Fistula Needle Set (Safety Series)**May 17, 2018  
359 days to decisionK171505 · Product code: **FIE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k171505/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	May 23, 2017
Decision date	May 17, 2018
Days to decision	359 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dimesol, Inc.</b>
Location	Lewisberry, PA, US
Contact	Stephen P. Callaghan
510(k) history	2 submissions · 2 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171505/> 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 May 30, 2026