

**K992653 SHELLY PROTECTED AV FISTULA NEEDLE**Oct 27, 1999  
82 days to decisionK992653 · Product code: **FIE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k992653/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Aug 6, 1999
Decision date	Oct 27, 1999
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Diasol, Inc.</b>
Location	North Hollywood, CA, US
Contact	MONICA ABELES
510(k) history	10 submissions · 10 cleared · 1999-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992653/> 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 7, 2026