

**K891062 TERUMO AV FISTULA NEEDLE SET**Jun 22, 1989  
113 days to decisionK891062 · Product code: **FIE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k891062/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Mar 1, 1989
Decision date	Jun 22, 1989
Days to decision	113 days
Third-party review	No

**APPLICANT**

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Company	<b>Terumo Medical Corp.</b>
Location	Elkton, MD, US
Contact	GEORGE S MOMODA
510(k) history	143 submissions · 143 cleared · 1980-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k891062/>; 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 27, 2026