

**K032127 HEMEDEX FIXATION DEVICE**Dec 30, 2003  
173 days to decisionK032127 · Product code: **KNY** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k032127/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Catheter, G-u (KNY)
Date received	Jul 10, 2003
Decision date	Dec 30, 2003
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hemedex Incorporated</b>
Location	Hopkinton, MA, US
Contact	DEBBIE IAMPIETRO
510(k) history	4 submissions · 4 cleared · 2002-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k032127/> 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 6, 2026