

**K970994 CORE AND COIL ASSEMBLY GUIDEWIRE**Mar 25, 1997  
6 days to decisionK970994 · Product code: **EZB** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k970994/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stylet For Catheter, Gastro-urology (EZB)
Date received	Mar 19, 1997
Decision date	Mar 25, 1997
Days to decision	6 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Lake Region Mfg., Inc.</b>
Location	Mchenry, IL, US
Contact	KIM AVES
510(k) history	42 submissions · 42 cleared · 1977-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970994/> 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 22, 2026