

**K180363 Clear-Tip EUS-FNA**Nov 1, 2018  
265 days to decisionK180363 · Product code: **FCG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k180363/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Feb 9, 2018
Decision date	Nov 1, 2018
Days to decision	265 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Finemedix Co., Ltd.</b>
Location	Daegu, KR
Contact	Heon Sik Lee
510(k) history	11 submissions · 11 cleared · 2018-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180363/> 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 25, 2026