

**K212423 EndoDrill® Model X**Mar 29, 2023  
602 days to decisionK212423 · Product code: **FCG** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k212423/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Biopsy Needle (FCG)
Date received	Aug 4, 2021
Decision date	Mar 29, 2023
Days to decision	602 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bibbinstruments AB</b>
Location	Lund, SE
Contact	Marie Grey
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan &amp; Lovells U.S. Lpp</b>
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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