

**K240781 SKOUT® system**Apr 19, 2024  
29 days to decisionK240781 · Product code: **QNP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k240781/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Mar 21, 2024
Decision date	Apr 19, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Iterative Scopes, Inc.</b>
Location	Cambridge, MA, US
Contact	Caitlyn Seidl
510(k) history	4 submissions · 4 cleared · 2022-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Janice Hogan

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240781/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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