

K251126 SKOUT systemMay 9, 2025
28 days to decisionK251126 · Product code: **QNP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k251126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Apr 11, 2025
Decision date	May 9, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Iterative Health
Location	Cambridge, MA, US
Contact	Caitlyn Seidl
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
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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