

K241508 SKOUT® systemJul 3, 2024
36 days to decisionK241508 · Product code: **QNP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k241508/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	May 28, 2024
Decision date	Jul 3, 2024
Days to decision	36 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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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