

K230658 SKOUT® systemApr 7, 2023
29 days to decisionK230658 · Product code: **QNP** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k230658/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Mar 9, 2023
Decision date	Apr 7, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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