FDA 510(k) Premarket Notification

K253664 SKOUT system

CLEARED

Dec 22, 2025
32 days to decision

K253664 · Product code: **QNP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k253664/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointesinal Lesion Software Detection System (QNP)
Date received	Nov 20, 2025
Decision date	Dec 22, 2025
Days to decision	32 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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Device record: https://www.510kdatabase.net/k253664/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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