

K213686 SKOUT SoftwareAug 12, 2022
263 days to decisionK213686 · Product code: **QNP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k213686/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Nov 22, 2021
Decision date	Aug 12, 2022
Days to decision	263 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213686/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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