FDA 510(k) Premarket Notification

K240781 SKOUT® system

CLEARED

Apr 19, 2024
29 days to decision

K240781 · Product code: **QNP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k240781/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointesinal Lesion Software Detection System (QNP)
Date received	Mar 21, 2024
Decision date	Apr 19, 2024
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	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