FDA 510(k) Premarket Notification

K252178 MAGENTIQ-COLO (ME-APDS)

CLEARED

Oct 3, 2025
84 days to decision

K252178 · Product code: **QNP** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k252178/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointesinal Lesion Software Detection System (QNP)
Date received	Jul 11, 2025
Decision date	Oct 3, 2025
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Magentiq Eye, Ltd.**
Location	Haifa, IL
Contact	Dror Zur
510(k) history	4 submissions · 4 cleared · 2023-2026

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John J. Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov