

**K244023 MAGENTIQ-COLO (ME-APDS)**Jan 24, 2025  
28 days to decisionK244023 · Product code: **QNP** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k244023/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Dec 27, 2024
Decision date	Jan 24, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	John J. Smith

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k244023/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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