

K223473 ME-APDS™Jul 25, 2023
250 days to decisionK223473 · Product code: **QNP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k223473/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gastrointestinal Lesion Software Detection System (QNP)
Date received	Nov 17, 2022
Decision date	Jul 25, 2023
Days to decision	250 days
Third-party review	No
Summary / Statement	Summary
Other names	MAGENTIQ-COLO™

APPLICANT

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

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