April 3, 2026

Magentiq Eye, Ltd.
% John J. Smith
Partner
Hogan Lovells US LLP
555 13th St., NW
Washington, District of Columbia 20004

Re: K260724
Trade/Device Name: MAGENTIQ-COLO (ME-APDS)
Regulation Number: 21 CFR 876.1520
Regulation Name: Gastrointestinal Lesion Software Detection System
Regulatory Class: Class II
Product Code: QNP
Dated: March 5, 2026
Received: March 5, 2026

Dear John J. Smith:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

SIVAKAMI VENKATACHALAM -S

for
Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260724

Please provide the device trade name(s).

MAGENTIQ-COLO (ME-APDS)

Please provide your Indications for Use below.

ME-APDS (Magentiq Eye's Automatic Polyp Detection System) is intended to be used by endoscopists as an adjunct to the common video colonoscopy procedure (screening and surveillance), aiming to assist the endoscopist in identifying lesions during colonoscopy procedure by highlighting regions with visual characteristics consistent with different types of mucosal abnormalities that appear in the colonoscopy video during the procedure. Highlighted regions can be independently assessed by the endoscopist and appropriate action taken according to standard clinical practice.

ME-APDS is trained to process video images which may contain regions consistent with polyps.

ME-APDS is limited for use with standard white-light endoscopy imaging only.

ME-APDS is intended to be used as an adjunct to endoscopy procedures and is not intended to replace histopathological sampling as means of diagnosis.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Magentiq Eye's MAGENTIQ-COLO

Submitter:
Magentiq Eye Ltd.
6 Ben-Gurion Blvd.,
Haifa, 3541416,
Israel

Phone: +972 (77) 2018838

Contact Person: Dr. Dror Zur

Date Prepared: March 5, 2026

Name of Device: Magentiq Eye's Automatic Polyp Detection System (ME-APDS™)

Trade Name: MAGENTIQ-COLO™

Common or Usual Name: Computer aided detection software for colorectal polyps

Classification Name: Gastrointestinal Lesion Software Detection System

Regulatory Class: II

Product Code: QNP

Predicate Device: Magentiq Eye's Automatic Polyp Detection System (K252178)

Device Description:

ME-APDS™/MAGENTIQ-COLO is intended to be used as an adjunct to the common video colonoscopy procedure. The system application aims to assist the endoscopist in identifying lesions, such as polyps, during the colonoscopy procedures in real time. The device is not intended to be used for diagnosis or characterization of lesions, and does not replace clinical decision making.

The system acquires the digital video output signal from the local endoscopy camera and processes the video frames. It runs deep machine learning and additional supporting algorithms in real time on the video frames in order to detect and identify regions having characteristics consistent with different types of mucosal abnormalities such as polyps. The output video with the detected lesions is presented on a separate screen, highlighting the suspicious areas on the original video. The user can also take snapshots of the videos, with and without the highlighting of the suspicious areas, record videos and view in full screen mode. The ME-APDS™ includes an additional feature that removes the presentation of the bounding box once the physician has inserted an endoscopic tool (e.g. snare or forceps) into the endoscopic field of view.

Intended Use / Indications for Use:

ME-APDS™ (Magentiq Eye's Automatic Polyp Detection System) is intended to be used by endoscopists as an adjunct to the common video colonoscopy procedure (screening and surveillance), aiming to assist the endoscopist in identifying lesions during colonoscopy procedure by highlighting regions with visual characteristics consistent with different types of mucosal abnormalities that appear in the colonoscopy video during the procedure. Highlighted regions can be independently assessed by the endoscopist and appropriate action taken according to standard clinical practice.

ME-APDS™ is trained to process video images which may contain regions consistent with polyps.

ME-APDS™ is limited for use with standard white-light endoscopy imaging only.

ME-APDS™ intended to be used as an adjunct to endoscopy procedures and is not intended to replace histopathological sampling as means of diagnosis.

Summary of Technological Characteristics:

Computer-Aided Polyp Detection (CADe) engine is the technological principle for both the subject and predicate devices. The major roles of CADe engine during colonoscopy is to process a video frame and to indicate the presence and location of detected lesions (such as polyps) in real time during colonoscopy procedure in order to improve mucosal lesion detection rates, thus improving the performance of the endoscopist.

The proposed device is a modification to the company cleared device. The AI Polyp detection algorithm has been revised following retraining of the neural network. In addition, there have been minor GUI changes. All other device features remain identical to the predicate device.

Performance Data:

Non-Clinical Testing:

The software validation of the subject device demonstrated that the ME-APDS functioned as intended and all tests' results observed were as expected.

Assessment of Marker Annotation Delay:

Marker annotation delay was assessed for all polyps from the standalone performance testing dataset. The marker annotation latency's median, calculated over all the polyps, is 0.166 sec for FHD and 0.190 sec for 4K.

Standalone Performance Testing:

The algorithm was tested offline on 252 unique full colonoscopy videos, containing 806 polyps. 24 videos contained no polyps. Of the 806 polyps, 660 were small ($s \leq 5mm$), 111 have medium size ($5mm < s < 10mm$), and 35 were large ($s \geq 10mm$). 375 polyps had histology findings where 302 were found to be adenoma polyps. Polyps evaluated varied by subject sex (270 Male, 170 Female, 366

Unknown), age (60 under 50 years, 133 50-60 years, 256 older than 60 years, 357unknown), race (343 Caucasian, 6 African American, 457 Unknown).

ME-APDS recall and false positive performance was evaluated. In addition, the number of False Positives Per Full Video (procedure) rate was assessed. Polyp-wise Recall was defined as the number of polyps detected, each for a set number consecutive frames, out of the total number of polyps in the testing dataset, Polyp-wise Recall was evaluated a 1, 3, 5 and 7 consecutive frames as Precall1, Precall3, Precall5, and Precall7, respectively. The system detects 99.7% to 99.2% (PRecall1 to PRecall7) of polyps verified by histology and 96.9% to 90.9% (PRecall1 to PRecall7) of the polyps when polyps without histology verification were included, showing the ability of the system to adequately aid in the detection of polyps when working with the MAGENTIQ-COLO. The median of the coverage of polyps with histology was high (85.8%). The False Positives Per Frame (FPPF) threshold of 0.0303 was achieved.

Results on polyps that were reported in the procedure report, classified according to polyps with histology and without.

Reported Results on Polyps with Histology and Without

-	FRecall	CI	MPC	PRecall1	CI	PRecall3	CI	PRecall5	CI	PRecall7	CI
With Histology	79.9%	[77.43%, 82.66%]	85.8%	99.7%	[99.17%, 100.0%]	99.5%	[98.63%, 100.0%]	99.2%	[98.24%, 100.0%]	99.2%	[98.21%, 100.0%]
Without Histology	77.4%	[73.48%, 81.58%]	79.3	98.9	[96.36%, 100.0%]	98.9%	[96.63%, 100.0%]	98.9%	[96.63%, 100.0%]	98.9%	[96.67%, 100.0%]

Results on the Entire Testing Dataset

FRecall	CI	MPC	PRecall1	CI	PRecall3	CI	PRecall5	CI	PRecall7	CI
76.7%	[74.57%, 79.14%]	78.2%	96.9%	[95.55%, 98.1%]	94.0%	[92.01%, 95.94%]	92.7%	[90.67%, 94.64%]	90.9%	[88.63%, 93.15%]

The Tool Detection feature was assessed and verified on a subset of the standalone performance testing database to demonstrate device performance is appropriately maintained.

In summary, the testing results were observed to be as expected and support that the device has similar performance to the predicate device.

Conclusions:

The modified ME-APDS/MAGENTIQ-COLO™ is as safe and effective as the company's prior cleared ME-APDS. The modified ME-APDS has the same intended uses and indications, similar technological characteristics, and same principles of operation as its predicate device. The minor differences do not alter the intended use and raise no new issues of safety or effectiveness. Performance data demonstrate that the modified ME-APDS is as safe and effective as the cleared ME-APDS. In addition, the clinical validation from the original K223473 submission is still applicable to the current modified device. Thus, the modified ME-APDS /MAGENTIQ-COLO™ is substantially equivalent.