



February 6, 2026

Median Technologies
% Laurence Boy-Machefer
VP Regulatory Affairs
1800 route des crêtes
VALBONNE, 06560
FRANCE

Re: K251474

Trade/Device Name: eyonis® LCS 1.1
Regulation Number: 21 CFR 892.2090
Regulation Name: Radiological Computer Assisted Detection And Diagnosis Software
Regulatory Class: Class II
Product Code: QDQ
Dated: January 6, 2026
Received: January 6, 2026

Dear Laurence Boy-Machefer:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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,

A handwritten signature in black ink that reads "Smita Kakar". The signature is written in a cursive style. In the background, there is a large, light blue, semi-transparent watermark of the letters "FDA".

for

Lu Jiang Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K251474

Device Name

eyonis® LCS 1.1

Indications for Use (Describe)

eyonis® LCS is indicated for use by radiologists. eyonis® LCS assists radiologists in the detection, localization and characterization of solid and part-solid probably benign, suspicious and very suspicious pulmonary parenchymal nodules with a diameter of 4-30 mm (pure ground glass, mediastinal lesions and masses - including but not limited to hilar masses - are excluded).

The eyonis® LCS - lung nodules result report provides, for each reported nodule, the following information: slice number, malignancy score, full snapshot, close-up snapshot, diameters (long/short/average) and volume.

The eyonis® LCS - lung nodules result report is indicated to aid in diagnosis as well as to aid in follow-up exam evaluations and as an adjunct to support clinical/patient management.

It cannot, however, substitute for medical experts' clinical judgment.

The target population is high-risk patients eligible for participation in lung cancer screening programs (as per USPSTF criteria) with the exception of patients with pure ground glass cancer only and hilar/mediastinal cancer who are excluded from the intended population.

It is indicated for use with low-dose Chest CT DICOM images. The exact specifications are described in a DICOM Conformance Statement (DCS) document.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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		Median Technologies	
Document Title: eyonisLCS1.1_K251474_510(k) Summary		Doc # eyonisLCS1.1_K251474_510(k) Summary	Version 01

1 Applicant Name and Address

Name: MEDIAN TECHNOLOGIES
Address: 1800 routes des crêtes, les 2 arcs, Bâtiment B
06560 Valbonne, France
Contact Person: Laurence BOY-MACHEFER, VP Regulatory Affairs

2 Summary Preparation Date: May 9th, 2025

3 Device Name and Classification

Trade Name	eyonis® LCS 1.1
Common name	AI/ML tech-based end-to-end CAdE/CADx Software as a Medical Device (SaMD) for Lung Cancer Screening
Device	Radiological Computer Assisted Detection/Diagnosis Software for Lesions Suspicious for Cancer
Class	Class II
Regulation Number	21 CFR 892.2090
Product Code	QDQ

4 Predicate Device

Trade Name	Transpara™ 2.1.0
Legal Manufacturer	ScreenPoint Medical B.V.
510(k) Number	K241831
Device	Radiological Computer Assisted Detection/Diagnosis Software for Lesions Suspicious for Cancer
Class	Class II
Regulation Number	21 CFR 892.2090
Product Code	QDQ

5 Device Description

eyonis® LCS is an AI/ML technology-based end-to-end CAdE/CADx Software as Medical Device (SaMD) intended to allow early detection, localization and characterization of pulmonary parenchymal nodules from LDCT DICOM images produced during Chest CT examinations.

The product consists of a Container-based Image Processing chain with no associated viewer. The software applies algorithms for detection, localization and characterization of solid and part-solid nodules. These algorithms employ proprietary AI and Machine Learning models trained with large databases containing proven examples of lung cancer lesions and benign nodules.

Processing results of eyonis® LCS are given in the form of a DICOM 'result report' which displays probably benign/suspicious/very suspicious nodules with a malignancy risk score per nodule, ranked by score and an associated malignancy rate observed in our reference population.

The result report is saved directly as a DICOM file for the purpose of being stored on a PACS system. It is transmitted back to the Median Gateway to be dispatched to a configured location, local hard drive or a DICOM Service class provider. Alternatively, Dicom Web and HL7 are supported.

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eyonis trust, a license server, addresses important challenges such as authorizing or revoking customer access to eyonis® LCS 1.1, tracking software usage, and ensuring legal compliance with licensing contracts.

eyonis® LCS output is not intended to replace the clinical judgment of the interpreting physician and should only be used along with clinical interpretation.

The software can be deployed in any environment that supports Kubernetes deployment (Cloud based or on premises) as a set of orchestrated containers.

Software deployment is flexible and allows 3 installation methods, depending on the infrastructure, resources and capabilities.

6 Intended Use

eyonis® LCS is an AI/ML technology-based end-to-end CAdE/CADx Software as a Medical Device (SaMD) designed to enable early detection, localization and characterization of pulmonary parenchymal nodules on low-dose Chest CT images in order to aid cancer diagnosis and improve clinical management of patients.

As an output, eyonis® LCS generates a result report that highlights probably benign, suspicious and very suspicious nodules and scores them individually by giving a malignancy score and an associated malignancy rate observed in the reference population.

It is intended to be used in a concurrent read mode, where the AI analysis results are displayed alongside the original CT images. eyonis® LCS' output is not intended to replace the critical judgement of the interpreting physician.

7 Indications for Use

eyonis® LCS is indicated for use by radiologists. eyonis® LCS assists radiologists in the detection, localization and characterization of solid and part-solid probably benign, suspicious and very suspicious pulmonary parenchymal nodules with a diameter of 4-30 mm (pure ground glass, mediastinal lesions and masses - including but not limited to hilar masses - are excluded).

The eyonis® LCS - lung nodules result report provides, for each reported nodule, the following information: slice number, malignancy score, full snapshot, close-up snapshot, diameters (long/short/average) and volume.

The eyonis® LCS - lung nodules result report is indicated to aid in diagnosis as well as to aid in follow-up exam evaluations and as an adjunct to support clinical/patient management.

It cannot, however, substitute for medical experts' clinical judgment.

The target population is high-risk patients eligible for participation in lung cancer screening programs (as per USPSTF criteria) with the exception of patients with pure ground glass cancer only and hilar/mediastinal cancer who are excluded from the intended population.

It is indicated for use with low-dose Chest CT DICOM images. The exact specifications are described in a DICOM Conformance Statement (DCS) document.

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8 Comparison of Technological Characteristics with the Predicate Device

eyonis® LCS has the same intended use as the predicate device. Both devices are intended to be used by clinicians interpreting radiological images, to help them with detecting, localizing and characterizing abnormalities. The devices are both intended to be used concurrently with the reading of images and are not intended as a replacement for the review of a clinician or their clinical judgement.

The indication for use of eyonis® LCS and the predicate device differ in the target organ and disease-specific findings the devices detect, the type of medical images the devices process, and the intended patient population. However, these differences do not raise new questions regarding safety and effectiveness of the device when used as labeled.

	Predicate Device (Transpara™ 2.1.0)	Subject Device (Median LCS/eyonis LCS)	Substantially Equivalent ?
Classification Regulation	21 CFR 892.2090 Radiological Computer Assisted Detection And Diagnosis Software	SAME	Yes, identical.
Medical Device Classification	Class II	SAME	Yes, identical
Product Code	QDQ	SAME	Yes, identical
Level of Concern	Moderate/Basic Level of Documentation	SAME	Yes, identical
Intended Use	A concurrent reading aid for Physicians interpreting screening images, to identify findings and assess their level of suspicion.	SAME	Yes, identical
Target patient Population	Screening population	SAME	Yes, identical
Target user population	Interpreting physician	SAME	Yes, identical
Design	Software-only device (Viewer optional)	SAME No viewer	Yes, identical
Score	Finding level: Continuous score 1-100 indicating the level of suspicion of malignancy (from low suspicion to high suspicion). Organ level: None Exam level:	Finding level: Discreet score 1-10 accompanied with malignancy rate (from probably benign to very suspicious) Organ level: None Exam level: None	Both devices' algorithms yield a continuous 100-point score, intended to be interpreted as likelihood of malignancy. The predicate provides the 100-point score directly to the user, while Median LCS provides a simplified 10-point score that is monotonic with the likelihood of malignancy. Substantially equivalent.

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	10-point scale score indicative of higher frequency of cancer positive.		
Interaction with findings	Upon user request by clicking in a position of the image also detected by Transpara™.	Findings are by-default displayed when score is equal or higher to 2.	Both are implementations of the same intention: reducing the number of findings the user has to review. Substantially equivalent.
Device output & user interface	Distinguishes two types of suspicious findings (calcifications and soft tissue lesions). The device output includes the location and the outline of findings. Transpara™ processing server is a standalone system WITHOUT a user interface.	Only targets one type of findings (nodules, solid/part-solid). Median LCS result report includes the localization (slice number), two snapshots, diameters and volume. Same.	Despite some differences between the predicate device and Median LCS, device output and user interface are still comparable and do not raise new questions regarding safety and effectiveness of the device.
Fundamental scientific technology	A chain of medical image processing and machine learning techniques are implemented. The device includes 'deep learning' modules for recognition of suspicious lesions. These modules are trained with very large databases of cancer and normal patients proven by biopsy or follow-up.	SAME	Yes, identical

The overall design of eyonis® LCS is similar to that of the predicate device. Differences in technological characteristics of eyonis® LCS and the predicate device do not raise different questions of safety and effectiveness.

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9 Software Verification and Validation

9.1 Voluntary FDA recognized standards and guidelines / Documentation level

In the design and development of eyonis® LCS 1.0, Median Technologies applied the following voluntary FDA recognized standards and guidelines:

Standard ID	Year / Edition	Standard Title	Recognition #
IEC 62366-1	Edition 1.1 2020-06	Medical devices - Part 1: Application of usability engineering to medical devices	5-129
ISO 20417	First edition 2021-04 Corrected Version 2021-12	Medical devices – Information to be supplied by the manufacturer	5-135
ISO 14971	Third Edition 2019-12	Medical Devices - Application Of Risk Management To Medical Devices	5-125
IEC 62304	Edition 1.1 2015-06	Medical Device Software - Software Life Cycle Processes	13-79
IEC 82304-1	Edition 1.0 2016-10	Health software - Part 1: General requirements for product safety	13-97
ISO 15223-1	Fourth edition 2021-07	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	5-134
NEMA PS 3.1 – 3.20 2023e	2023 edition	Digital Imaging and Communications in Medicine (DICOM) Set	12-352

The following guidance documents were used to support this submission:

ID	Year	Title
FDA-1997-D-0029	2002	General Principles of Software Validation
FDA-2011-D-0652	2014	The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
FDA-2015-D-5105	2016	Postmarket Management of Cybersecurity in Medical Devices
FDA-2011-D-0469	2016	Applying Human Factors and Usability Engineering to Medical Devices
FDA-2015-D-4852	2017	Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices
FDA-2014-D-0456	2018	Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
FDA-2018-D-1329	2019	Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions
FDA-2018-D-1339	2020	Multiple Function Device Products: Policy and Considerations: Guidance for Industry and Food and Drug Administration
FDA-2016-D-1853	2021	Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)
FDA-2019-D-1470	2022	Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions
FDA 2021-D-1158	2023	Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
FDA-2021-D-0775	2023	Content of Premarket Submissions for Device Software Functions
FDA-2019-D-3598	2023	Off-The-Shelf Software Use in Medical Devices
FDA-2023-D-1030	2023	Cybersecurity in Medical Devices: Refuse to Accept Policy for Cyber Devices and Related Systems Under Section 524B of the FD&C Act
FDA-2021-D-0872	2023	Electronic Submission Template for Medical Device 510(k) Submissions

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eyonis® LCS is a software-only device, aka Software as a Medical Device (SaMD). The recommended documentation level is Basic Documentation Level.

9.2 Non-clinical Performance Testing

Software verification and validation testing were conducted to provide evidence that eyonis® LCS meets user needs and its intended use. Testing results demonstrate that the software specifications meet acceptance criteria.

A standalone performance test was executed on eyonis® LCS to demonstrate generalizability and performance endpoints on a retrospective cohort study that evaluated eyonis® LCS SaMD across a larger, and enriched cohort of 1,147 patients (342 cancers, 805 non-cancer cases) from 7 different datasets (2 academic sites in Europe, 3 academic sites in the United States and 2 private American data providers). The dataset was enriched for cancer prevalence, nodules size and spiculation. A 1:2 cancer to benign ratio was chosen to ensure that sufficient cancer cases were available to statistically power the endpoints, but to also ensure that there was adequate sampling of the non-cancerous population which is very heterogeneous. The study population met stringent eligibility criteria, focusing on high-risk individuals aged 50 to 80 with a history of smoking. LDCT exams were analyzed with the CADe/CADx and the output (LCS report) compared to radiologist consensus. Reference standard proven via histopathology or ≥12 months stability.

The Clinical Operating Threshold (COT) for the Standalone study was pre-determined prior to study execution as the threshold between LCS scores 3 and 4 of the device eyonis® LCS.

In the Standalone study described above, eyonis® LCS achieved:

- a patient-level AUROC of 0.904 [0.881-0.926] $p < 0.0001$ (acceptance criterion: AUROC > 0.800),
- a sensitivity at COT of 84.50% [80.22-88.17] $p < 0.0001$ (acceptance criterion: sensitivity at COT > 70%),
- a specificity at COT of 80.25% [77.33-82.95] $p < 0.0001$ (acceptance criterion: specificity at COT > 70%),
- an AULROC of 0.869 [0.843-0.894] $p < 0.0001$ (acceptance criterion: AULROC > 0.750) which confirms eyonis® LCS' localization capability.

As part of exploratory analyses, FROC analysis yielded a sensitivity at COT of 80.59% [76.20-84.49] and a false-positive rate of 0.271 [0.235-0.313] per scan.

9.3 Clinical Performance Testing

A pivotal reader study has been conducted to determine whether the performance of radiologists in detecting and characterizing lung nodules increases when they use eyonis® LCS – Lung nodules result report compared to when they read LDCT unaided.

Median Technologies conducted a Paired-Split Plot (PSP) multi-readers, multi-cases (MRMC) retrospective reader study to assess the impact of eyonis® LCS on reader performance in detecting pulmonary nodules on chest low dose CT images. The study consisted of 16 clinical readers (13.31 mean year of experience, from 2 to 32 years of experience) and 480 total patient images. The subject population was composed of patients from across the United States as well as from Europe. The readers participating in the study were all US Board Certified radiologists from multiple regions within

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the US with varied years of experience and specialties. They were de-identified for the purposes of the study.

The study was conducted sequentially to simulate use of the product in clinical practice. In each block of 120 patients, readers interpreted each patient twice: unaided (control arm) and aided by eyonis® LCS (test arm), in a random order.

For the control arm, radiologists were asked to interpret the images as they would in standard clinical practice and note findings with a bounding box and associated level of confidence in their interpretation.

The study compared unaided and aided radiologist performance at detecting pulmonary nodules, localizing them and characterizing as compared to the reference standard. The primary objective of the study was to determine whether the accuracy of readers aided by eyonis® LCS was significantly superior to the accuracy of readers unaided as determined by the image-level Area Under the Curve (AUC) of the Receiver Operating Characteristic (ROC) curve.

For the MRMC study, a clinically relevant threshold allows to separate a patient that would continue as per normal (annual screening visit) and a patient for whom the follow-up is changed (screening frequency increased). It corresponds to the notion of 'recall rate'. Follow-up decisions were collected directly from the radiologists in the eCRF, recall rates are based on those collected decisions.

The study successfully met its primary objective, demonstrating that the use of eyonis® LCS result report significantly improved radiologist's diagnostic performance compared to using the scan alone:

- Acceptance criterion: ΔAUC (aided – unaided) > 0, $p < 0.05$
- Results: aided AUC = 0.8434 / unaided AUC = 0.8276 / ΔAUC (aided – unaided) = 0.0158 [0.0032-0.0288], $p = 0.0277$.

Secondary endpoints were as follows:

- Sensitivity:
 - o Acceptance criterion: $\Delta sens$ (aided-unaided) > 0,
 - o Results: sens aided = 93.75% / sens unaided = 92.50% / $\Delta sens$ (aided-unaided) = 1.25 [-1.52-4.02] ($p > 0.05$, non-significant)
- Specificity:
 - o Acceptance criterion: $\Delta spec$ (aided-unaided) > 0,
 - o Results: spec aided = 53.59% / spec unaided = 49.45% / $\Delta spec$ = 4.14 [0.27-8.01] ($p < 0.05$, significant)

The study met the secondary superiority objective of specificity and the secondary non-inferiority objective of sensitivity (numerically superior but not statistically significant for the superiority test), thus confirming that the specificity is significantly improved in the eyonis® LCS arm (clinical benefit) whilst the sensitivity is not different between aided and unaided arms (patient safety preserved).

Further clinical benefits were also explored:

- Increase of inter-reader agreement per patient score: ICC Reader aided = 0.830 [0.800-0.856] / ICC Reader unaided = 0.707 [0.659-0.749] / $p < 0.0001$
- Increase of inter-reader agreement per patient management: Kappa value reader aided = 0.4898 [0.4527-0.5270] / Kappa value reader unaided = 0.3507 [0.3147-0.3867] / $p < 0.05$
- Sub-analysis on US patients: ΔAUC = 0.017 [0.006-0.028], $p < 0.05$

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10 Conclusions

The data presented in this 510(k) includes all required information to support the review by FDA. Non-clinical and clinical performance tests demonstrate that eyonis® LCS is safe and effective.

One difference with the predicate device is a difference in the indications for use, because it detects different disease specific findings in different radiological images. The risks associated with the use of the device are comparable because they are both intended to be used in a similar way as aid for the clinician. Median Technologies has applied a risk management process in accordance with FDA recognized standards to identify, evaluate, and mitigate all known hazards related to eyonis® LCS. These hazards may occur when accuracy of diagnosis is potentially affected, causing either false-positives or false-negatives. All identified risks are effectively mitigated and it can be concluded that the residual risk is outweighed by the benefits.

Results of the primary analysis of the clinical test demonstrate that use of eyonis® LCS improves diagnosis of lung cancer in LDCT images.

The special controls for CAdE/CAdx are satisfied by demonstrating effectiveness of the device in both the standalone testing and the clinical MRMC testing, showing superiority of aided versus unaided reads in clinical testing. The technological differences between eyonis® LCS and the predicate device do not raise concerns of safety and effectiveness.

Considering all data in this submission, the data provided in this 510(k) supports the safe and effective use of eyonis® LCS its indications for use and substantial equivalence to the predicate device.