



September 29, 2026

Elucid Bioimaging, Inc.
Windi Hary
Chief Quality and Regulatory Officer
399 Boylston St., Suite 400
Boston, Massachusetts 02116

Re: K262015

Trade/Device Name: Elucid FFR-IQ (B.1)
Regulation Number: 21 CFR 870.1415
Regulation Name: Coronary Vascular Physiologic Simulation Software Device
Regulatory Class: Class II
Product Code: PJA
Dated: August 28, 2026
Received: August 31, 2026

Dear Windi Hary:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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,

STEPHEN C. BROWNING -S

CDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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.

K262015

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Please provide the device trade name(s).

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Elucid FFR-IQ (B.1)

Please provide your Indications for Use below.

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Elucid FFR-IQ is a coronary physiological simulation software for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography DICOM data for clinically stable patients with suspected coronary artery disease. It provides FFR-CT (CT-derived FFR) values computed from coronary CTA images using AI-enabled algorithms. FFR-IQ is intended to support the functional evaluation of coronary artery disease.

The FFR-IQ results are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. FFR-IQ results are intended to be used by qualified clinicians in conjunction with the with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment.

Please select the types of uses.

☒ Prescription Use ([21 CFR 801 Subpart D](#))

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

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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)

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510(k) Summary

Submitter Information

Submitter / Manufacturer Name	Elucid Bioimaging, Inc. 399 Boylston Street, Suite 400, Boston, MA 02116
Primary Correspondent & Contact Information	Windi Hary Chief Regulatory and Quality Officer Email ID: windi.hary@elucid.com
Secondary Correspondent & Contact Information	Hiral Vora Lead Quality and Regulatory Affairs Specialist Email ID: hiral.vora@elucid.com
Date Prepared	September 29, 2026

Device Identification

Proprietary Name	Elucid FFR-IQ (B.1)
Device Classification Name	Coronary vascular physiologic simulation software device
Regulation Description	Coronary vascular physiologic simulation software device
Regulation Number	870.1415
Device Class	Class II
Product Code	PJA
Device Characteristics	Device is software as a service
Environment of Use	Healthcare Facility / Hospital / Physician Office

Predicate Device

Proprietary Name	Heartflow FFRct
Device Classification Name	Coronary vascular physiologic simulation software device
Regulation Description	Coronary vascular physiologic simulation software device
510(k) Number	DEN130045
Regulation Number	870.1415
Device Class	Class II
Product Code	PJA
Device Characteristics	Device is software as a service
Environment of Use	Healthcare Facility / Hospital / Physician Office

Intended Use

Elucid FFR-IQ is a coronary physiological simulation software for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography DICOM data for clinically stable patients with known or suspected coronary artery disease. It provides FFR-CT (CT-derived FFR) values estimated from coronary CTA images using AI-enabled algorithms. FFR-IQ is intended to support the functional evaluation of coronary artery disease.

The FFR-IQ results are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. FFR-IQ results are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment.

Device Description

FFR-IQ is a BioIntegrated coronary physiological software for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography DICOM data for clinically stable patients with known or suspected coronary artery disease. It integrates anatomy and biology (such as plaque composition and amount which impacts vasodilation) to estimate FFR-CT values from static coronary CTA images with extracted coronary tree structures using deep learning neural networks. Elucid's FFR-IQ analysis is intended to support the functional evaluation of Coronary Artery Disease. Using the 3D segmentation results of Plaque-IQ, an AI-enabled algorithm assesses FFR-CT (CT-derived FFR) values along the coronary tree.

Elucid's FFR-IQ is deployed and controlled by Elucid. FFR-IQ is AI-enabled.

Summary of Technological Characteristics

Comparison Criteria	Subject Device	Predicate Device	Comparison Assessment
	Elucid FFR-IQ (B.1)	HeartFlow FFRct v1.4	-
510(k)	K262015	DEN130045	-
Manufacturer	Elucid Bioimaging, Inc	HeartFlow, Inc.	-
Product Code	PJA	PJA	Same as predicate
Regulation	870.1415	870.1415	Same as predicate
Device Classification Name	Coronary vascular physiologic simulation software device	Coronary vascular physiologic simulation software device	Same as predicate
Device Class	II	II	Same as predicate
Input / Data Source	CT / K241524 (CT)	CT	Similar, however Elucid FFR-CT requires the output of K241524 as input
Output	Graphics and text results of noninvasively derived FFR-CT that can be	Graphics and text results of noninvasively derived FFR-CT that can be	Same as predicate

Comparison Criteria	Subject Device	Predicate Device	Comparison Assessment
	accessed by end users/physicians using a device with internet connectivity	accessed by end users/physicians using a device with internet connectivity	
Ground Truth for Model Training	Paired CT and invasive FFR data	Paired CT and invasive FFR data	Same

Summary of Nonclinical Performance Data

Software verification and validation testing was conducted and documentation provided as recommended in FDA guidance *Content of Premarket Submissions for Device Software Functions*.

Cybersecurity testing was conducted and documentation provided as recommended in FDA guidance document *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*.

Human Factors and Usability testing was conducted and documentation provided as recommended in FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices*.

Results of all current and previously referenced testing concludes the device is acceptable for use.

Risk Management

Risk management was conducted and documentation provided as recommended in FDA guidance *Content of Premarket Submissions for Device Software Functions* and in accordance with *ISO 14971 Medical Devices – Applications of risk management to medical devices*.

Summary of Clinical Validation

Study Design

ELUCIDATE (NCT06018194) is a retrospective, multicenter study that included eleven study sites in the US (9) and OUS (2), representative of a generalized population and real-world use conditions.

Elucid designed this retrospective study to reflect expected commercial performance, rather than the performance of a prospective study where CT image acquisition and invasive FFR data collection protocols are rigorously supervised, controlled, and unlikely to represent real-world conditions.

The retrospective study design required paired CCTA and invasive FFR for validation purposes; however, the population receiving invasive FFR is necessarily narrower than the population receiving FFR-CT due to the referral pathway that produces both diagnostic tests on the same patient. Under AHA/ACC guidance (Lawton et al. 2021) invasive FFR is performed only when non-invasive assessment cannot resolve the clinical question, predominantly intermediate 40-69% diameter stenosis. The retrospective validation cohort requiring paired CCTA and invasive FFR is therefore drawn from that referred subset and is enriched for borderline disease and significantly weighted in the FFR gray zone of 0.75 - 0.85. The US dataset reflects this enriched population; therefore, the US dataset and subsequent performance reflect a more challenging intended use population than the broader population expected commercially.

Elucid enrolled data from an OUS site which previously collected the data prospectively to represent the portion of the population that is deferred from further invasive assessment. The prospective study protocol under which the data was originally acquired encouraged invasive FFR measurement in all territories regardless of disease state. Thus, clearly non-obstructive, non-ischemic vessels are supplemented where retrospective data is sparse. Differences in the prospective data collection (as defined by the collection protocol for that study) drive differences in the disease prevalence between the US and OUS sites, as well as between the retrospectively and prospectively collected data. To this end, the performance results are reported for the US cohort, the OUS cohort, and the overall validation cohort respectively.

Subjects ages 18 and over with clinically indicated CCTA and invasive FFR performed within 60 days of CCTA. Study design ensured blinding of FFR-CT processing to invasive FFR. The study analyzed 491 vessels across 347 patients.

Enrollment exclusion criteria for patients included:

- Prior coronary artery bypass graft (CABG) or percutaneous intervention (PCI)
- History of myocardial infarction prior to CCTA and/or invasive FFR
- Known complex congenital heart disease
- Existing pacemaker or internal defibrillator lead implantation
- Existing prosthetic heart valve
- Interval clinical myocardial infarction, diagnosis of decompensated heart failure, stroke, or coronary revascularization between CCTA and invasive FFR

Additional exclusion criteria related to data necessary for analysis included:

- Missing CCTA for analysis
- Missing invasive coronary angiography imaging or adequate description defining the position of the invasive FFR wire location
- Non-diagnostic CCTA or invasive FFR
- Poor CCTA image quality that does not meet Elucid image processing requirements for plaque and FFR-CT
- CCTA or invasive FFR performed prior to January 1, 2012
- Absence of study date for CCTA or invasive FFR
- Patients who had IFR or CFR, and not measured FFR

FFR-IQ was used to simulate FFR-CT from the subject's CT. The FFR-CT was then compared to the invasively collected FFR to assess the device performance.

Primary Safety and Effectiveness Endpoints

The primary endpoints regarding this study were sensitivity and specificity to have the lower limits of their 95% CI to be > 75%. These performance goals were not necessarily determined to be sufficient for substantial equivalence, but the performance demonstrated by the results was.

Study Results

The ELUCIDATE overall study results as well as the separate US cohort met the primary endpoints.

Per vessel	US cohort results	Overall Results	NXT Predicate results
Sensitivity	90.9 [85.1, 96.5]	92.2 [87.5, 96.5]	84 [75, 89]
Specificity	89.2 [83.9, 93.7]	93.1 [90.2, 95.6]	86 [82, 89]
Unadjusted PPV	84.1 [77.7, 90.5]	84.4 [79.2, 89.3]	61 [53, 69]
Unadjusted NPV	94.0 [90.0, 97.6]	96.7 [94.8, 98.5]	95 [93, 97]
Bland-Altman LoA	0.19 [-0.09 - 0.10]	0.23 [-0.10 - 0.13]	0.30 [-0.12 - 0.18]
Sample size	N = 257	N = 491	N = 484

Due to the retrospective nature of the study, there were no adverse events or complications observed in the study.

Conclusion

While there are differences noted in the technological characteristics of the proposed device and the predicate device, namely that the predicate uses computational fluid dynamics and the subject device does not, the differences do not raise different questions of safety or effectiveness. Non-clinical verification and validation, along with clinical performance data, collectively support substantial equivalence of the subject device to the predicate.