October 8, 2026

Neuroxt, Inc.
Sunyoung Kim
Regulatory Affairs Team Leader
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Seoul, 04799
Republic Of Korea

Re: K261805
Trade/Device Name: NEXT-Cue
Regulation Number: 21 CFR 882.1454
Regulation Name: Prognostic Assessment Software Of Mild Cognitive Impairment
Regulatory Class: Class II
Product Code: QWT
Dated: May 31, 2026
Received: June 1, 2026

Dear Sunyoung Kim:

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,

Patrick Antkowiak -S

Patrick Antkowiak, PhD
Assistant Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K261805

Device Name
NEXT-Cue

Indications for Use *(Describe)*
NEXT-Cue is a software application indicated as a prognostic tool to aid in the clinical assessment of patients aged 55 through 88 years who are diagnosed with mild cognitive impairment (MCI) and are being evaluated for progression to clinical Alzheimer's disease (AD) dementia within five years of assessment.

NEXT-Cue analyzes inputs of brain magnetic resonance imaging (MRI), patient demographic information, and cognitive assessment scores to produce a similarity score between 0 and 100 reflecting the degree of similarity between the patient and two reference populations of MCI patients who either did not progress to clinical AD-dementia within 5 years (non-converters) or progressed to clinical AD-dementia within 5 years (converters).

NEXT-Cue is intended to be used in clinical environments by trained healthcare professionals as a supplementary tool, and its outputs are meant to support, not replace, comprehensive clinical evaluation and must be interpreted alongside clinical history, physician examination, and other diagnostic tests. NEXT-Cue is not intended to be used as a diagnostic tool for MCI or Alzheimer's disease.

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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# NEXT-Cue 510(k) Summary

This 510(k) Summary is being provided in accordance with 21 CFR 807.92.

**1. Submitter Information**

Submitter: NeuroXT Inc.

Address: 917-919, 48, Achasan-ro 17-gil, Seongdong-gu, 04799 Seoul, Republic of Korea.

Contact Person: Sunyoung Kim, Leader, Regulatory Affairs Team.

Phone: +82 10 7416-2337.

Email: sykim@neuroxt.com.

**2. Device Name**
Trade/Proprietary Name: NEXT-Cue.

Common/Usual Name: Brain imaging analysis software.

Classification Name / Regulation: Prognostic assessment software for mild cognitive impairment, 21 CFR 882.1454.

Product Code: QWT.

**3. Predicate Device**
The predicate device for this submission is BrainSee, DEN220066.

**4. Device Description**
NEXT-Cue is a software-only medical device that provides artificial intelligence-supported analysis of T1-weighted structural brain MRI and selected clinical information to support prognostic assessment in patients with mild cognitive impairment (MCI). The software receives input data including T1-weighted structural brain MRI, patient demographic information, and cognitive assessment scores, and processes these data using automated image analysis and machine learning-based algorithms.

Based on these inputs, NEXT-Cue generates a similarity score between 0 and 100 reflecting the degree of similarity between the patient and two reference populations of MCI patients who either did not progress to clinical Alzheimer's disease (AD) dementia within 5 years (non-converters) or progressed to clinical AD dementia within 5 years (converters). NEXT-Cue supports clinical workflows through case management, automated analysis-status tracking, report generation, and report-delivery functions.

**5. Intended Use and Indications for Use**
NEXT-Cue is a software application indicated as a prognostic tool to aid in the clinical assessment of patients aged 55 through 88 years who are diagnosed with mild cognitive impairment (MCI) and are being evaluated for progression to clinical Alzheimer's disease (AD) dementia within five years of assessment.
NEXT-Cue analyzes inputs of brain magnetic resonance imaging (MRI), patient demographic information, and cognitive assessment scores to produce a similarity score between 0 and 100 reflecting the degree of similarity between the patient and two reference populations of MCI patients who either did not progress to clinical AD-dementia within 5 years (non-converters) or progressed to clinical AD-dementia within 5 years (converters).
NEXT-Cue is intended to be used in clinical environments by trained healthcare professionals as a supplementary tool, and its outputs are meant to support, not replace, comprehensive clinical evaluation and must be interpreted alongside clinical history, physician examination, and other diagnostic tests. NEXT-Cue is not intended to be used as a diagnostic tool for MCI or Alzheimer's disease.

**6. Substantial Equivalence Comparison**
NEXT-Cue is compared with the predicate device, BrainSee (DEN220066), with respect to regulatory classification, indications for use, intended patient and user populations, prescription-use status, clinical role, and technological characteristics. Both devices combine structural brain MRI, demographic information, and cognitive assessment

information to generate a 0–100 similarity score for supplementary prognostic assessment of progression to clinical Alzheimer's disease dementia within five years.

The comparison below identifies similarities and differences in the devices' labeling and implementation. NEXT-Cue is indicated for patients aged 55 through 88 years diagnosed with mild cognitive impairment (MCI), whereas BrainSee is indicated for patients aged 55 through 95 years diagnosed with amnestic mild cognitive impairment (aMCI). These labeling differences are identified explicitly and considered together with the clinical performance evidence and limitations described in Section 7.

The regulatory, intended-use, user-related, and technological characteristics of NEXT-Cue and BrainSee are summarized below.

| **Device Characteristic** | **NEXT-Cue** | **Predicate Device: BrainSee** | **Comparison and Assessment** |
|---|---|---|---|
| Intended Use / Clinical Purpose | Supplementary prognostic assessment to aid clinical evaluation of progression from MCI to clinical AD dementia within five years. | Supplementary prognostic assessment to aid clinical evaluation of progression from aMCI to clinical AD dementia within five years. | Similar prognostic purpose and time horizon. The difference in labeled patient-population terminology is identified below. Neither device is intended to replace comprehensive clinical evaluation. |
| Indications for Use | NEXT-Cue is a software application indicated as a prognostic tool to aid in the clinical assessment of patients aged 55 through 88 years who are diagnosed with mild cognitive impairment (MCI) and are being evaluated for progression to clinical Alzheimer's disease (AD) dementia within five years of assessment.<br>NEXT-Cue analyzes inputs of brain magnetic resonance imaging (MRI), patient demographic information, and cognitive assessment scores to produce a similarity score between 0 and 100 reflecting the degree of similarity between the patient and two reference populations of MCI patients who either did not progress to clinical AD-dementia within 5 years (non-converters) or progressed to clinical AD-dementia within 5 years (converters).<br>NEXT-Cue is intended to be used in clinical environments by trained healthcare professionals as a supplementary tool, and its outputs are meant to support, not replace, comprehensive | BrainSee is a software application indicated as a prognostic tool to aid in the clinical assessment of how likely patients aged between 55 and 95 years old who are diagnosed with amnestic mild cognitive impairment (aMCI) are to progress to clinical Alzheimer's disease (AD)-dementia within 5 years of assessment. BrainSee analyzes inputs of brain magnetic resonance imaging (MRI), patient demographic information, and cognitive assessment scores to produce a similarity score between 0 and 100 reflecting the degree<br>of similarity between the patient and two reference populations of aMCI patients who either did not progress to clinical AD-dementia within 5 years (non-converters) or progressed to clinical AD-dementia within 5 years (converters). Clinical AD-dementia is defined as probable Alzheimer's disease established according to the National Institute of Neurological and Communicative Disorders and Stroke — Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) Alzheimer's Criteria.<br>•Similarity scores less than 50 indicate that a patient's inputs are | Similar supplementary prognostic purpose, input modalities, and similarity-score output. Differences include the labeled cognitive-impairment population, age range, and device-specific output-interpretation wording. These differences are considered with the submitted clinical performance evidence and labeling limitations. |

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| | clinical evaluation and must be interpreted alongside clinical history, physician examination, and other diagnostic tests. NEXT-Cue is not intended to be used as a diagnostic tool for MCI or Alzheimer's disease. | more similar to those of the non-converter population.<br>•Similarity scores greater than 50 indicate that a patient's inputs are more similar to those of the converter population.<br>•Patients with a similarity score close to 50 have inputs that are similar to both the converter and non-converter aMCI patient populations used to develop and train the BrainSee device.<br>The similarity score output is provided along with information to assist in the interpretation of the output to aid in evaluating the prognosis of patients diagnosed with aMCI to progress to clinical AD-dementia within 5 years.<br>The BrainSee analysis is intended to provide supplemental information for interpretation in conjunction with a standard neurological assessment. Patient management decisions should not be made solely on the results of the BrainSee analysis. BrainSee is not indicated as a stand-alone diagnostic or prognostic tool. BrainSee should not be used to diagnose aMCI. | |
| Intended Patient Population | Patients aged 55 through 88 years with a clinical diagnosis of MCI who are being evaluated for progression to clinical AD dementia within five years. | Patients aged 55 through 95 years with a diagnosis of aMCI who are being evaluated for progression to clinical AD dementia within five years. | Different labeled age ranges and cognitive-impairment population terminology. NEXT-Cue's age range falls within the predicate's age range. MCI and aMCI are not represented as identical patient-population labels; the clinical evidence and its limitations are described in Section 7. |
| Intended User Population | Trained healthcare professionals in clinical environments. Primary clinical interpretation is performed by appropriately qualified clinicians responsible for assessment and management of patients with MCI. | Clinicians using BrainSee to supplement clinical assessment of patients with aMCI. | Similar professional clinical-user setting. NEXT-Cue's submitted user-role description distinguishes primary clinical interpretation from technical imaging-support functions. |
| Intended User / User Role | A trained healthcare professional interprets the output together with clinical history, physician examination, cognitive assessment, neuroimaging, and other relevant diagnostic | A clinician reviews the similarity-score output as supplemental information in conjunction with a standard neurological assessment. Patient-management decisions must not be based solely on the BrainSee analysis. | Similar clinician-led interpretation and non-standalone clinical role. Device-specific workflow and role assignments do not transfer clinical decision- |

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| | information. Technical imaging-support personnel may support MRI/PACS workflow and report access but do not independently interpret the score as a patient-specific prognosis. | | making responsibility to the software. |
| Prescription Use Only | Yes. Prescription use only; not intended for over-the-counter use. | Yes. Prescription use under 21 CFR 801.109. | Same prescription-use status. |
| Intended Use Environment | Clinical environments with access to required MRI and clinical information; web-based software with clinical report delivery. | Cloud-based platform accessed by clinicians through a web portal for clinical information entry, MRI upload, and report review. | Similar clinical use of a cloud-based software platform. Device-specific differences in data transfer and report-delivery workflow are addressed through software and interoperability verification. |
| Device type | Cloud-based software-only medical device | Cloud-based software-only medical device | Similar. Both devices are software-based prognostic assessment tools. |
| Input data | T1-weighted structural brain MRI, patient demographic information, and cognitive assessment scores | T1-weighted brain MRI, patient age and sex, and cognitive/behavioral assessment scores, including MMSE and CDR-Sum of Boxes | Similar. Both devices combine structural brain MRI, demographic information, and cognitive assessment information. |
| Image analysis | Automated image analysis of T1-weighted structural brain MRI and machine learning-based processing | Automated processing of standard 3-dimensional T1-weighted brain MRI to derive brain tissue volumes | Similar fundamental technological approach. Both devices use automated quantitative analysis of structural brain MRI as part of the prognostic assessment workflow. |
| Algorithm | Machine learning-based algorithm operating in a locked configuration | Proprietary software algorithm generating a similarity score from MRI and clinical inputs | Similar. Both use algorithmic processing of MRI and clinical inputs to generate a prognostic similarity output. |
| Output | Similarity score between 0 and 100, reflecting similarity to MCI non-converter and converter reference populations | Similarity score between 0 and 100, reflecting similarity to aMCI non-converter and converter reference populations | Similar. Both devices provide a 0–100 similarity score for supplementary prognostic assessment. |
| User access and workflow | Web-based access with case management, automated analysis-status tracking, report generation, and delivery through the clinical workflow | Web-based platform for entering clinical information, uploading MRI data, and viewing, downloading, or printing the output report | Difference in workflow implementation. Both devices provide software-based access to a prognostic report. NEXT-Cue workflow functions are controlled through software verification and validation, interoperability testing, cybersecurity controls, and risk management. |
| User control of algorithm | Model configuration, model weights, operating threshold, and score transformation | Algorithmic processing is performed by the software; users provide required input | Similar. Users do not modify the algorithmic basis of the prognostic output during clinical use. |

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| | rule are locked and not user-modifiable | information and review the output report | |
| Clinical role | Supplementary prognostic tool; output must be interpreted with clinical history, physician evaluation, and other relevant diagnostic information | Adjunctive prognostic tool; not intended as a stand-alone diagnostic or prognostic tool | Similar. Neither device is intended to replace comprehensive clinical evaluation or serve as a stand-alone diagnostic tool. |
| Regulatory Classification | Proposed Class II classification under 21 CFR 882.1454, Prognostic assessment software of mild cognitive impairment; Product Code: QWT. | Class II under 21 CFR 882.1454, Prognostic assessment software of mild cognitive impairment; Product Code: QWT. | NEXT-Cue's proposed regulatory classification, regulation number, and product code match those of the predicate. |

Differences between NEXT-Cue and BrainSee include the labeled patient population and age range, as identified in the comparison table, as well as device-specific implementation of the software workflow, user interface, report delivery, and algorithm configuration. These differences do not alter the fundamental technological characteristics of the devices: both are software-based tools that combine structural brain MRI, demographic information, and cognitive assessment information to generate a 0–100 similarity score for supplementary prognostic assessment.
The performance, software verification and validation, interoperability, cybersecurity, risk management, and human factors evidence provided in this submission support that the technological differences do not raise different questions of safety and effectiveness.

**7. Clinical Performance Data**
Clinical performance evaluation of NEXT-Cue included internal validation, external validation, and subgroup analysis using pre-specified converter/non-converter reference classifications. The clinical performance evaluation assessed the ability of the locked NEXT-Cue configuration to generate a Prognitor Score for supplementary prognostic assessment of progression from MCI to clinical AD dementia.

Performance endpoints included area under the receiver operating characteristic curve (AUROC), sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Sensitivity, specificity, PPV, and NPV were evaluated at the fixed operating threshold corresponding to Prognitor Score 50.

| Study | Study Design and Population | Endpoint | Results | Conclusion |
|---|---|---|---|---|
| Internal Validation | Five-fold subject-level cross-validation using an ADNI development cohort of 1,407 subjects. Five-year converter/non-converter performance was evaluated using pooled out-of-fold predictions from 487 subjects who met the pre-specified evaluation criteria. | AUROC; sensitivity, specificity, PPV, and NPV at Prognitor Score 50. | AUROC: 0.9350; sensitivity: 71.43%; specificity: 95.34%; PPV: 95.89%; NPV: 68.66% | The internal-validation results provide supportive development evidence within the pre-specified evaluable cohort. |
| External Validation | Independent ADNI holdout cohort of 180 subjects from 12 held-out U.S. sites, with no overlap with the 54 training sites used for model development. The original classification analysis used the pre-specified converter/non-converter reference labels and was not censoring-adjusted. | AUROC; sensitivity, specificity, PPV, and NPV at Prognitor Score 50. | AUROC: 0.9142; sensitivity: 71.91%; specificity: 97.80%; PPV: 96.97%; NPV: 78.07% | The original external-validation results are presented together with the updated censoring-adjusted analysis below and are interpreted subject to the stated study limitations. |

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| Subgroup Analysis | Subgroup analyses of the external validation cohort | Performance assessment by available demographic and clinical subgroup | Results are summarized in the Performance Test Report and interpreted in consideration of the available sample size and outcome distribution for each subgroup. | Subgroup findings are presented with applicable sample-size, outcome-distribution, and statistical-interpretability limitations. Subgroups with insufficient sample sizes or single-class outcomes are not interpreted as providing reliable subgroup-specific performance estimates. |

**Censoring-Adjusted Performance Through 60 Months**

A censoring-adjusted Kaplan–Meier analysis was conducted in the original 180-subject external-validation cohort to evaluate NEXT-Cue's performance through 60 months while accounting for incomplete follow-up. Original index visits, locked Prognitor Scores, and the pre-specified operating threshold of Prognitor Score 50 were retained. No subject was excluded based on follow-up duration. Subjects without an observed qualifying conversion event by 60 months were right-censored at the earlier of their last valid CDR assessment or 60 months after the index visit. The results are summarized below.

| Metric | Estimate | Two-sided 95% Confidence Interval |
|---|---|---|
| Censoring-adjusted sensitivity | 71.3% | 61.6%–80.9% |
| Censoring-adjusted specificity | 93.7% | 88.5%–98.0% |
| Five-year PPV | 90.9% | 82.5%–96.3% |
| Five-year NPV | 78.8% | 70.0%–85.3% |

In the censoring-adjusted analysis through 60 months, the sensitivity point estimate was 71.3%, exceeding the pre-specified 70% sensitivity criterion on a point-estimate basis. However, the lower bound of the two-sided 95% confidence interval was 61.6%, below that criterion. Accordingly, these results do not demonstrate that sensitivity exceeds 70% with 95% confidence. This uncertainty reflects the cohort size and observed event distribution. The analysis also relies on the assumption that censoring is non-informative within each Prognitor Score group, conditional on observed data.

This sensitivity estimate and its associated uncertainty are considered clinically acceptable in the context of NEXT-Cue's supplementary role because patients with MCI receiving a false-negative output are likely to receive continued clinical evaluation and longitudinal follow-up for their MCI condition. Furthermore, the NEXT-Cue algorithm is tuned to favor specificity over sensitivity to reduce false-positive outputs. NEXT-Cue's output must be interpreted together with clinical history, physician evaluation, and other relevant diagnostic information and must not be used as the sole basis for discontinuing follow-up or making patient-management decisions. A lower-score output does not exclude progression to clinical AD dementia and must not be used to defer otherwise clinically indicated evaluation, cognitive and functional monitoring, referral, diagnostic work-up, or management.

PPV and NPV are prevalence-dependent; the observed converter proportion in the external validation cohort is a cohort-specific outcome composition and is not presented as the expected five-year converter prevalence in routine clinical practice.

The external validation cohort was derived from ADNI research sites and does not fully represent all demographic groups, clinical practice settings, routine MRI workflows, scanner/protocol combinations, or follow-up conditions encountered in U.S. clinical practice. The subgroup findings are descriptive and do not establish equivalent performance across demographic strata. The sponsor has committed to prospective non-ADNI U.S. post-market evidence generation for the locked released configuration.

The Prognitor Score is a similarity score and is not an individual patient-specific probability of progression to clinical AD dementia.

**8. Nonclinical Performance Data**

Nonclinical testing and assessments were performed to verify that NEXT-Cue meets its specified software, image-quality, interoperability, cybersecurity, usability, and risk-management requirements. The results are summarized below.

| Test Category | Applicable Standard or Method | Results | Conclusion |
|---|---|---|---|
| Image Quality Control Validation | Staged image quality control framework applied to 436 3D T1-weighted MRI scans | The framework achieved an overall catch rate of 82.1% for non-conforming scans and maintained 100.0% specificity and 100.0% precision for block decisions in the locked framework. | Image quality control functions appropriately identified non-conforming scans and prevented inappropriate input data from proceeding to analysis. |
| Software Verification and Validation | Verification and validation against specified software requirements, including unit, integration, and system-level testing | NEXT-Cue v1.0.0.0 met specified requirements and intended-use requirements. Overall software validation result: PASS. | Software functions were verified and validated for the submitted configuration. |
| Interoperability and Workflow Verification | Verification of EHR/PACS-related data handling, analysis-status tracking, report generation, and report delivery functions | Required workflow functions, status handling, failure handling, and report-delivery functions were verified for the submitted configuration. | The device supports the intended automated clinical workflow with defined status, failure, and recovery controls. |
| Cybersecurity Verification and Risk Management | Cybersecurity lifecycle controls, access control, audit logging, session management, software update controls, and applicable risk-management activities | Security-related controls were verified for the submitted configuration. Residual cybersecurity risks were evaluated through the risk-management process. | Cybersecurity controls support controlled access, traceability, and secure operation within the intended use environment. |
| Human Factors / Usability Assessment | Risk-based human factors and usability assessment, including use-related risk analysis of the intended users, use environments, user interface, and foreseeable use errors. | The use-related risk analysis identified no critical tasks that, if performed incorrectly or not performed at all, could reasonably foreseeably result in serious harm to patients. | The assessment supports that human factors validation testing data are not needed to support the substantial equivalence determination for NEXT-Cue. |
| Risk Management | Risk-management process in accordance with the Risk Management Plan and applicable risk-management procedures | Residual risks were evaluated as acceptable. Limited AFAP process residual risks were accepted and monitored through post-market surveillance. | The overall residual risk was considered acceptable in relation to the intended use and expected benefits of NEXT-Cue. |

The nonclinical performance evidence supports that NEXT-Cue meets its specified requirements and that the submitted device configuration provides appropriate controls for image quality, software operation, clinical workflow, cybersecurity, usability, and use-related risks.

**9. Substantial Equivalence**

Both NEXT-Cue and BrainSee are software-based devices that use structural brain MRI, demographic information, and cognitive assessment information to generate a 0–100 similarity score for supplementary prognostic assessment of progression from mild cognitive impairment to clinical AD dementia. The devices use different patient-population terminology in their respective labeling; the intended-use comparison and associated rationale are provided in the substantial equivalence comparison table.

The comparison presented in Section 6 identifies similarities in regulatory classification, prescription-use status, clinical purpose, and technological characteristics, and identifies differences in labeled patient populations, age ranges, and device-specific implementation. The implementation differences relate primarily to device-specific software workflow, user interface, report generation and delivery, and implementation of the locked algorithm configuration.

The performance, software verification and validation, image-quality control, interoperability, cybersecurity, human factors, and risk-management evidence provided in this submission support that the identified technological differences do not raise different questions of safety and effectiveness. Accordingly, NEXT-Cue is considered substantially equivalent to BrainSee.