October 2, 2026

Argus Cognitive, Inc.
Andrea Marosan
Director of Quality-Regulatory Affairs
35 S. Main St.
Hanover, New Hampshire 03755

Re: K260064
Trade/Device Name: Neurora
Regulation Number: 21 CFR 882.1491
Regulation Name: Pediatric Autism Spectrum Disorder Diagnosis Aid
Regulatory Class: Class II
Product Code: QPF
Dated: September 4, 2026
Received: September 4, 2026

Dear Andrea Marosan:

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
DHT5A: Division of Neurosurgical,
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Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260064

Device Name
Neurora

Indications for Use *(Describe)*
Neurora is indicated for the non-intrusive quantification and reporting of biometrics derived from video and audio recordings collected during semi-structured behavioral assessment sessions to aid healthcare professionals in the diagnosis of ASD in patients aged 18 months through 12 years; Neurora is intended for use in conjunction with the diagnostic process and is not a stand-alone diagnostic tool.

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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510(k) SUMMARY

Neurora Software as a Medical Device

General Information [807.92(a)(1)]

Submitter:
Argus Cognitive, Inc.
35 South Main street, Hanover, NH 03755
www.arguscognitive.com

Contact person:
Andrea Marosan
Director, Quality-Regulatory Affairs
andi@arguscognitive.com

Submission date: January 8, 2026 - *updated on September 04, 2026*

Submission type: 510(k) - New Device

510(k) number: k260064

Establishment Registration Number: 3036502204

Device Information [807.92(a)(2)]

Trade Name: Neurora

Generic Name: Pediatric Autism Spectrum Disorder diagnosis aid

Classification: 21 CFR 882.1491

Product Code: QPF

Device Class: Class II

Predicate Device(s) [807.92(a)(3)

DEN200069 - Cognoa ASD Diagnosis Aid

Device Description [807.92(a)(4)]

Device characteristics

Neurora is a **standalone Software as a Medical Device (SaMD)** operating as a web-based Software as a Service (SaaS) platform. It is not part of a hardware medical device and operates independently as cloud-based diagnostic support software.

Environment of use

Healthcare facility/Hospital: Neurora is intended for use by healthcare professionals who are qualified to conduct semi-structured behavioral assessments, interpret behavioral assessment results, and diagnose ASD.

General description

Neurora is a software as a medical device (SaMD) designed to aid in the diagnosis of Autism Spectrum Disorder (ASD) by utilizing multiple machine-learning algorithms to measure behavioral outcomes in a post-assessment environment. To measure biometrics during ASD assessments, Neurora relies on a pair of glasses with a central forward-facing camera to record the clinician's field of view, along with off-the-shelf microphones to record audio. Users will then upload audio and video recordings to a web portal as input data. Neurora analyzes this data to detect vocal patterns, body movements, facial expressions, and gaze. The system processes temporal event data to calculate duration metrics and occurrence frequencies, then uses AI/ML algorithms to analyze these patterns against validated diagnostic criteria to generate an autism spectrum disorder output for healthcare professionals. The analysis results are visually displayed and stored in a patient manager along with other patient data.
The device is intended to provide information for use by the care professional, in conjunction with other clinically relevant information, to assist in the diagnosis of ASDs.

The Neurora System consists of the following components:

- Neurora Web Portal: A user interface (UI) enabling healthcare professionals (HCPs) to upload video and audio recordings from structured behavioral assessment sessions. It interfaces with the Application Programming Interface (API) server for the secure transmission and management of patient data.
    - Video/Audio Analyst Portal: A UI for HCPs to remotely review patient videos and audio analysis results, verify or correct observed behaviors, and access patient evaluation results.
    - Outcome Report: Following the AI/ML analysis, the system generates a comprehensive report based on patterns identified by the Neurora Engine. This report provides:
        - Autism Spectrum Disorder (ASD) Result:
            - The system evaluates the behavioral patterns detected by the Neurora Engine during the semi-structured interview to generate the ASD Result, the system's estimation of the presence of ASD based on the model's output. The ASD Result should be interpreted

by qualified healthcare professionals in conjunction with other clinical measures and their professional judgment.

- Neurora API: This component shall act as an interface between the Neurora Engine and the Web Portal. It should expose the functionalities of the engine in such a way that they can be utilized in the web frontend.
- Neurora Engine: An artificial intelligence software module that processes audio data for prosodic vocal expressions and video data for facial and eye movement patterns. It quantifies these patterns to generate biometrics

Intended use and Indications for Use [807.92(a)(5)]

Intended Use: Neurora is intended for use by healthcare professionals as an aid in diagnosis and assessment of Autism Spectrum Disorder (ASD).

Indications for Use: Neurora is indicated for the non-intrusive quantification and reporting of biometrics derived from video and audio recordings collected during semi-structured behavioral assessment sessions to aid healthcare professionals in the diagnosis of ASD in patients aged 18 months through 12 years; Neurora is intended for use in conjunction with the diagnostic process and is not a stand-alone diagnostic tool.

Neurora's intended use population (18 months through 12 years) is broader than the predicate's (18 months through 6 years). This difference is not critical to the diagnostic use of the device or affects its safety and effectiveness when used as labeled, as detailed under **Comparison of Technological Characteristics [807.92(a)(6)]** below.

Comparison of Technological characteristics with the Predicate Devices [807.92(a)(6)]

The following table compares the technological characteristics of Neurora to the predicate device, Cognoa ASD Diagnosis Aid (DEN200069), and identifies where the devices differ.

Category	Predicate Device Cognoa ASD Diagnosis Aid	Subject Device Neurora	Comparison
General Comparison			
Submission Number	DEN200069	[k260064]	
Regulation Number and Regulation Name	21 CFR 882.1491 Pediatric Autism Spectrum Disorder diagnosis aid	21 CFR 882.1491 Pediatric Autism Spectrum Disorder diagnosis aid	Equivalent
Classification Product Code	QPF	QPF	Equivalent
Class	Class II	Class II	Equivalent
Classification Panel	Neurology (882)	Neurology (882)	Equivalent
Intended Use	Intended for use as an aid in the diagnosis of ASD.	Neurora is intended for use by healthcare professionals as an aid in diagnosis and assessment of Autism Spectrum Disorder (ASD).	Similarities: Both the Predicate Device and the Subject device is intended for non-intrusive objective evaluation of ASD symptoms of a child by using software to analyze the child's behavior in response to external stimuli. Both are intended for use in the evaluation of young children. Differences: While the predicate device's indications for use statement specifies 'diagnosis,'

Category	Predicate Device Cognoa ASD Diagnosis Aid	Subject Device Neurora	Comparison
			the subject device includes both diagnosis and assessment of ASD characteristics. Assessment refers to the same diagnostic evaluation process applied to patients who have already received an ASD diagnosis, consistent with clinical practice where the diagnostic tools are used to support ongoing clinical decision-making about ASD characteristics. This is a clarification, and not a significant change.
Indications for Use	The Cognoa ASD Diagnosis Aid is intended for use by healthcare providers as an aid in the diagnosis of ASD for patients ages 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare Provider. The device is not intended for use as a stand-alone diagnostic device but as an adjunct to the diagnostic process.	Neurora is indicated as an aid healthcare professionals in the diagnosis of ASD in patients aged 18 months through 12 years; Neurora is intended for use in conjunction with the diagnostic process and is not a stand-alone diagnostic tool.	Differences: • Age range (Subject device offers a wider range)
Intended User Group	The Device is intended for use by healthcare professionals trained and	Neurora is intended for use by healthcare professionals who are	Identical to predicate device

Category	Predicate Device Cognoa ASD Diagnosis Aid	Subject Device Neurora	Comparison
	qualified to interpret the results of a behavioral assessment examination and to diagnose ASD.	qualified to conduct semi-structured behavioral assessments, interpret behavioral assessment results, and diagnose ASD.	
Intended Use Population	Patients ages 18 months through 72 months	Infant (from 18 months to 2 years of age) Child (from 2 years to 12 years of age)	Differences: • Age Range (Neurora offers a wider range)
Clinical decision	Made by healthcare provider	Made by healthcare provider	Identical to predicate device
Technical Comparison			
Device description	The Cognoa ASD Diagnosis Aid is a software as a medical device (SaMD) that utilizes a machine-learning algorithm that receives independent information from caregivers or parents, trained analysts, and healthcare professionals (HCPs) to aid in the diagnosis of ASD.	Neurora is a software as a medical device (SaMD) that utilizes a machine-learning algorithm to detect and analyze biometrics by processing video and audio data collected by healthcare professionals (HCPs) to aid in the diagnosis of ASD during a semi-structured behavioral assessment. The system operates non-intrusively, without requiring the patient to remain stationary or interact directly with the equipment.	Differences: The subject device does not receive information from caregivers or parents. The subject device's description includes additional technical detail about specific biometrics analyzed (e.g., facial landmarks, gaze, speech patterns, etc) but this represents elaboration rather than fundamental functional difference.

Category	Predicate Device Cognoa ASD Diagnosis Aid	Subject Device Neurora	Comparison
Device architecture	It consists of multiple software applications and hardware platforms. Input data is acquired via a Mobile App, a Video Analyst Portal, and a HCP Portal.	System components: • Neurora Web Portal: A user interface (UI) enabling healthcare professionals (HCPs) to upload video and audio recordings • Video/Audio Analyst Portal: A UI for HCPs to remotely review patient videos and audio analysis results, verify or correct observed behaviors, and access patient evaluation results. • Outcome Report: Following the analysis, the system generates a comprehensive report based on patterns identified by the Neurora Engine.	Equivalent. Both are multi-component software systems with HCP portals for data input, review interfaces, and automated reporting. Architectural differences are minor implementation variations that do not affect safety or effectiveness.
Data collection	Data collected using normal commercially available camera to videotaped behavior.	Data is collected using commercially available cameras, including wearable glasses with integrated forward-facing cameras (worn by the clinician) to record the session from the clinician's field of view.	Equivalent

Category	Predicate Device Cognoa ASD Diagnosis Aid	Subject Device Neurora	Comparison
Technology	The Cognoa ASD Diagnosis Aid is a software as a medical device (SaMD) that utilizes a machine-learning algorithm.	Neurora is a software as a medical device (SaMD) that utilizes a machine-learning algorithm.	Equivalent
Data output	If the value is greater than the upper threshold, then the device output is 'Positive for ASD.' If the value is less than the lower threshold, then the device output is 'Negative for ASD.' If the available information does not allow the algorithm to render a reliable result, the device output is 'No Result.'	The system evaluates the biometrics detected by the Neurora Engine during the semi-structured interview to provide a binary classification of the subject's behavior: ● ○ "Consistent with ASD" ○ "Not consistent with ASD"	Difference: Neurora does not include a 'No result' output. Every assessed patient receives a binary classification.
Design	SaMD	SaMD	Identical to predicate device
Software / Cybersecurity	MODERATE level of concern. Documentation includes a threat model, cybersecurity mitigation information, an upgrade and maintenance plan, and other	MODERATE level of concern Documentation includes all relevant information as required by the FDA Guidance "Content of Premarket Submissions for	Identical to predicate device

Category	Predicate Device Cognoa ASD Diagnosis Aid	Subject Device Neurora	Comparison
	information for safeguarding the device algorithms.	Management of Cybersecurity in Medical Devices": threat modeling, cybersecurity controls, security assessment using CVSS scoring system, and other information for safeguard and data protection.	
Performance Characteristics			
Safety	Adverse events (AEs) and serious adverse events (SAEs) were collected and reported from enrollment through completion of the reference diagnosis clinic visit.	Safety monitoring protocol was implemented as part of the clinical studies. All adverse events and serious adverse events were collected, documented, and assessed from enrollment through study completion per FDA guidance and IRB requirements, including the external US cohort collected across the five additional sites..	Identical to predicate device
Electrical Safety Testing	N/A as the device is a SaMD.	Not applicable (SaMD on general computing platform)	Identical to predicate device
Test data	Data available to show safety and effectiveness	Data available to show safety and effectiveness - See NEU-V&V - Populations and databases document.	Equivalent

Category	Predicate Device Cognoa ASD Diagnosis Aid	Subject Device Neurora	Comparison
Overall ASD classification quality	When measured on all clinical study completers: Sensitivity: 51.6% [95% CI 42.4 - 60.8] Specificity: 18.5% [95% CI 14.3 - 23.3] For the 31.8% of participants who received a determinate output (ASD positive or negative): Sensitivity 98.4% [95% CI 91.6%–99.96%] Specificity 78.9% [95% CI 67.6%–87.7%]	New external US test cohort (Multisite US Independent Test set, n=173): Sensitivity 70.59% [63.08-78.13%], Specificity 83.78% [70.27-94.87%], PPV 94.12% [89.11-98.15%], NPV 43.66% [32.05-55.26%]. 100% of assessed subjects received a determinate binary classification (0% no-result rate)	Neurora's new-cohort performance (sensitivity 70.59%, specificity 83.78%, 100% of assessed subjects receiving a determinate result) is compared against two predicate benchmarks. FDA's De Novo summary for the predicate reports performance only on the 31.76% of subjects who received a determinate output (sensitivity 98.44% [95% CI 91.60%–99.96%], specificity 78.87% [95% CI 67.56%–87.67%]); no all-completers figure is reported there directly. An all-completers estimate (sensitivity 51.64%, specificity 18.48%) can be derived from the confusion matrix in FDA's own De Novo summary (FDA, 2020) by scoring "No Result" as negative; the same estimate, with confidence intervals, is also reported in Megerian et al. (2022).
No response rate	68.24%	0% no response rate - system always provides a result	Differences: Neurora provides an output for every subject as opposed to the predicate device that gives a “No result” output for 68% of the subjects.

Category	Predicate Device Cognoa ASD Diagnosis Aid	Subject Device Neurora	Comparison
Clinical reference standard	DSM-5 criteria, determined by majority assessment of up to three specialists: diagnosis by a site-specific specialist, followed by independent review by one or two central specialist clinicians, with majority rule resolving disagreement.	DSM-5 criteria, established through clinical evaluation — administration of an age- and language-appropriate ADOS-2, caregiver/guardian interview, and review of developmental and medical history — integrated by a single qualified diagnosing clinician. Assessment components may be administered by trained assisting personnel under the diagnosing clinician's supervision. The reference standard diagnosis was finalized independently of, and prior to, any Neurora output.	Differences: The predicate requires independent central-reviewer confirmation for every case, with majority rule among up to three specialists. Neurora's reference standard relies on a single diagnosing clinician integrating ADOS-2, caregiver interview, and developmental history. There is no routine second-reviewer consensus step, and inter-rater agreement was not calculated across the study population. Both reference standards apply DSM-5 criteria through structured, validated assessment processes and were established independently of, and prior to, exposure to the device output.
Other			
Labeling	The labeling is sufficient and satisfies the requirements of 21 CFR 801.109 for prescription devices.	Meets the requirements of 21 CFR 801.109 for prescription devices.	Equivalent to predicate device
Bench testing	Non-clinical or bench testing was generally not needed to evaluate the hardware that the software is intended to be run on.	Bench testing was generally not needed to evaluate the hardware that the software is intended to be run on.	Equivalent to predicate device

Neurora's software design leverages and expands upon the technological capabilities of the predicate device, Cognoa ASD Diagnosis Aid (DEN200069), while maintaining substantial equivalence.

Key Software Features and Comparisons:

- **Expanded Age Range:** Neurora is designed to support ASD assessment in children aged 18 months to 12 years. This expands upon the age range of the predicate device: Cognoa is limited to children up to 6 years old. Clinical performance was evaluated across chronological age subgroups spanning the full intended use range, including the 18–36-month subgroup (n=30 ASD, n=4 non-ASD; sensitivity 83.33% [95% CI: 68.75-96.43%], specificity 100%), as detailed in the **Clinical Validation Report (Table 1.)**. These results do not indicate that the expanded age range introduces a safety or effectiveness concern distinct from the predicate's.
- **Data Acquisition and Analysis:** Neurora utilizes video and audio recordings, captured using readily available, off-the-shelf devices, to collect data during semi-structured clinician-child interactions. This approach aligns with Cognoa in utilizing digital data for analysis but expands the modalities captured. The recorded data is then analyzed automatically to derive objective behavioral measurements. This automated analysis contrasts with Cognoa's reliance on manual data entry and annotation by parents, caregivers, and HCPs.
- **Output Reporting and Clinical Interpretation:** Neurora provides a classification to support clinician assessmentof "Consistent with ASD" or "Not Consistent with ASD."
    - This output format differs from the predicate, Cognoa, which provides a binary categorical output ("Positive for ASD" / "Negative for ASD") with a "No Result" category. Both devices, however, provide quantitative decision support intended to assist — but not replace — clinical judgment. Neither output directly determines or controls a diagnostic or treatment decision. Neurora maintains the same intended use and clinical function. Therefore, this difference in output reporting does not raise new questions of safety or effectiveness and is considered substantially equivalent.

The subject device, Neurora, has the same intended use and equivalent technological characteristics, performance, and safety profile as the legally marketed predicate device. Minor differences in implementation details (e.g., data collection methods, user interface design, age range extension) do not raise new questions of safety or effectiveness.

Therefore, Neurora is substantially equivalent to Cognoa ASD Diagnosis Aid (DEN200069) and may be marketed for its intended use.

Performance Data [807.92(b)]

Performance testing conducted to support a determination of substantial equivalence included nonclinical testing — software verification and validation, analytical validation, and cybersecurity assessment — and clinical testing, summarized below.

Nonclinical Testing Summary [807.92(b)(1)]

Software verification

Software verification was performed at the unit, integration, and system levels, in accordance with the FDA's General Principles of Software Validation and ISO 13485:2016. Unit-level testing evaluated individual software modules using black-box and white-box test strategies; integration testing evaluated the complete system with all components operating concurrently. System-level testing assessed analytical engine processing time, user interface response time, availability, and behavior under concurrent load: both audio and video analysis workflows completed well within the applicable 24-hour turnaround requirement; average response time (0.7 seconds) met the 5-second success criterion; the system achieved 100% uptime over a 30-day monitoring period; and the system remained stable under concurrent-load testing, with response times increasing under high-concurrency conditions.

Analytical validation

Analytical validation assessed Neurora's individual algorithmic modules (vocalization/speaker diarization, facial action unit detection, and person/face detection) against benchmark datasets and an independently annotated human ground-truth dataset, using module-specific, pre-specified success criteria grounded in published literature. Inter-rater reliability of the ground-truth annotations was confirmed using Cohen's Kappa (≥0.7 across annotated event types). All evaluated modules met their pre-specified success criteria.

Cybersecurity

All necessary cybersecurity testing was conducted on Neurora to support safe and secure operation as a web-based Software as a Medical Device. Security assessment activities were performed in accordance with FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (April 2022) and "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" (October 2018).

Security testing demonstrated that Neurora implements appropriate security controls for a Tier 2 medical device. No critical or high-severity vulnerabilities were identified during testing. All security-critical functions including authentication, authorization, data encryption, and secure communications operate as intended.
Low-severity findings identified during testing were evaluated and determined to be acceptable within the device's Tier 2 classification and risk profile.

Clinical Testing Summary [807.92(b)(2)]

Clinical Studies

Clinical validation of Neurora's output consisted of a multicenter clinical validation study of the binary ASD classification and a supportive reader study evaluating clinician interaction with the Neurora report. The final user-facing report provides one of two binary results: "Consistent with ASD" or "Not Consistent with ASD."

Multisite Clinical Validation Study

Study Design

The primary clinical validation study was a multicenter, blinded, non-interventional study conducted at five clinical sites in the United States: Denver, Colorado; Dallas, Texas; Houston, Texas; Baton Rouge, Louisiana; and Phoenix, Arizona. The study evaluated Neurora in children aged 18 months through 12 years who were undergoing evaluation for ASD or developmental and behavioral concerns, together with typically developing comparison subjects.

The clinical validation population was independent of the data used for model development at both the subject and clinical-site levels. There was no overlap in subjects, clinical sites, or healthcare providers between the development datasets and the independent test set.

A total of 202 subjects were enrolled. Of these, 173 met the predefined clinical, recording-quality, assessment-completeness, reference-standard requirements, did not withdraw consent and were included in the primary diagnostic-performance analysis. The analyzed population included 136 subjects with an ASD reference diagnosis and 37 subjects in the combined Non-ASD reference group, comprising 22 subjects with a Non-ASD clinical condition and 15 typically developing subjects.

The analyzed population included 59 female and 114 male subjects. Mean chronological age was 60.60 months (SD 28.43), with a range of 18 to 144 months. 80 subjects were evaluated using the ADOS-2 Toddler Module or Module 1, 37 using Module 2, and 56 using Module 3.

Clinical Reference Standard

The clinical reference diagnosis was established independently of Neurora by licensed psychologists with expertise in the evaluation and diagnosis of ASD, each with at least five years of experience in diagnosing autism.

The reference-standard assessment incorporated the Autism Diagnostic Observation Schedule, Second Edition (ADOS-2), developmental and medical history, caregiver information, direct clinical observation, and application of DSM-5 diagnostic criteria. The ADOS-2 classification alone did not determine the reference diagnosis. One final diagnosing clinician integrated the available clinical information and assigned the reference-standard outcome as ASD, Non-ASD clinical condition, or Typically developing.

When the individual diagnostic inputs were not concordant, the diagnosing clinician reviewed all available information, obtained additional information when clinically indicated, and applied DSM-5 criteria to determine the final diagnosis. The reference diagnosis was finalized and locked before the clinician or assisting personnel had access to any Neurora output, and the evaluation was conducted under double-blind conditions, such that Neurora also had no knowledge of the reference diagnosis. For evaluation of Neurora's binary classification, the Non-ASD clinical and Typically developing categories were combined into a single Non-ASD reference group.

Primary Performance Endpoint

The primary performance endpoint evaluated the sensitivity and specificity of Neurora's binary output relative to the locked clinical reference diagnosis. The analysis population consisted of 173 subjects with evaluable Neurora results and an established clinical reference diagnosis. Neurora generated a valid binary classification for all 173 subjects in the analysis population, corresponding to a no-result rate of 0%.

Clinical Performance Results

Overall sensitivity was 70.59% (95% CI: 63.08-78.13%), and specificity was 83.78% (95% CI: 70.27-94.87%), and balanced accuracy was 77.19% (95% CI: 69.62-84.03%).

Positive predictive value was 94.12% (95% CI: 89.11–98.15%), negative predictive value was 43.66% (95% CI: 32.05–55.26%). These predictive values reflect the 78.61% ASD prevalence of the validation population and should be interpreted in that context. At a prevalence of 70.9%, representative of children referred for ASD evaluation in U.S. clinical settings [Klaiman, C., White, S., Richardson, S. et al. Expert Clinician Certainty in Diagnosing Autism Spectrum Disorder in 16–30-Month-Olds: A Multi-site Trial Secondary Analysis. J Autism Dev Disord 54, 393–408 (2024). https://doi.org/10.1007/s10803-022-05812-8], prevalence-adjusted positive and negative predictive values are 91.38% and 53.90%, respectively, calculated from Neurora's observed sensitivity and specificity.

When compared to the predicate, Cognoa (CanvasDx), the sensitivity and specificity of the Neurora device are higher than of the predicate device.

Table 1. Comparison in sensitivity and specificity between Neurora and the predicative device.

Population	Sensitivity Mean (n/N) 95% CI	Specificity Mean (n/N) 95% CI
Cognoa (CanvasDx (mITD)) N=425	51.6% (63/122) 42.8% - 60.5%	18.5% (56/303) 14.3% - 23.3%)
Neurora N=173	70.6% (96/136) 63.1%-78.1%	83.8% (31/37) 70.3-94.9%

Safety

The clinical validation study was non-interventional. The Neurora output was not used to establish the clinical reference diagnosis or to direct treatment during the study. Neurora is intended to provide adjunctive information to qualified healthcare professionals and is not intended to establish or exclude an ASD diagnosis independently of a comprehensive clinical evaluation. No device-related adverse events or complications were reported during the clinical validation study.

Summary

The independent multisite clinical validation study demonstrated an overall sensitivity of 70.59% and specificity of 83.78% for Neurora's binary ASD classification, with a valid result generated for every subject in the analysis population. The predefined binary-classification acceptance criterion based on comparison with the predicate device's whole-population performance estimates was met.

Taken together, the clinical validation results support use of Neurora's binary classification as an adjunct to, and not a replacement for, qualified clinical judgment in the evaluation of patients aged 18 months through 12 years who are being assessed for ASD.

CONCLUSION AND SUBSTANTIAL EQUIVALENCE STATEMENT

Neurora is substantially equivalent to the predicate device based on:

1. **Similar Intended Use:** Both provide adjunctive diagnostic support for ASD in pediatric populations to healthcare providers in clinical settings

2. **Similar Fundamental Scientific Technology:** Both employ machine-learning algorithms to analyze behavioral information and generate a diagnostic classification for ASD, based on video-derived and/or clinician- and caregiver-reported inputs

3. **Performance Characteristics:** Neurora's specificity is comparable to the predicate's reported performance (83.78% vs. 78.87%). Sensitivity is lower than the predicate's determinate-subset figure (70.59% vs. 98.44%) but exceeds the predicate's performance when evaluated on an all-completers basis, consistent with Neurora providing a classification for 100% of assessed patients rather than the predicate's 31.8%. These differences do not raise new questions of safety or effectiveness.

4. **Equivalent Safety Profile:** Both operate as software-only devices with minimal risk profile due to adjunctive labeling and clinical oversight requirements

The technological enhancements in Neurora (multi-modal analysis including audio, extended age range, advanced ML architectures) do not raise different questions of safety and effectiveness. These enhancements provide improved clinical utility while maintaining the fundamental operating principles and risk profile of the predicate device.

Verification, validation, cybersecurity, and clinical testing demonstrate that Neurora is safe and effective for its intended use and is substantially equivalent to the predicate device.