April 11, 2025

Cognoa, Inc.
% Alexia Haralambous
Senior Principal
RQM+
2790 Mosside Blvd, #800
Monroeville, Pennsylvania 15146

Re: K243558
Trade/Device Name: Canvas Dx
Regulation Number: 21 CFR 882.1491
Regulation Name: Pediatric Autism Spectrum Disorder Diagnosis Aid
Regulatory Class: Class II
Product Code: QPF
Dated: March 12, 2025
Received: March 12, 2025

Dear Alexia Haralambous:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not

required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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,

Jay R. Gupta -S

Jay Gupta
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional, and
Neurodiagnostic Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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.

Submission Number *(if known)*

K243558

Device Name

Canvas Dx

Indications for Use *(Describe)*

Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder (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.

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.

510(k) Summary

510(K) SUMMARY

DATE PREPARED
March 10, 2025

MANUFACTURER AND 510(k) OWNER
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DEVICE INFORMATION
Proprietary Name/Trade Name: Canvas Dx
Common Name: Pediatric Autism Spectrum Disorder diagnosis aid
Regulation Number: 21 CFR 882.1491
Class: II
Product Code: QPF
Premarket Review: OHT5/DHT5A
Review Panel: Neurology

PREDICATE DEVICE IDENTIFICATION
Canvas Dx is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
DEN200069	Cognoa ASD Diagnosis Aid / Cognoa, Inc.	✓

DEVICE DESCRIPTION
Canvas Dx is a prescription diagnostic aid for healthcare professionals (HCP) considering the diagnosis of Autism Spectrum Disorder (ASD) in patients 18 months through 72 months of age at risk for developmental delay. The subject device is identical to the Cognoa ASD Diagnosis Aid which was authorized under DEN200069 and was renamed Canvas Dx shortly thereafter. Canvas Dx consists of Software as a Medical Device (SaMD) together with several medical device data system (MDDS) components. The SaMD components consist of the following:

- Device inputs:
  - Device Input 1: The answers to the Caregiver Questionnaire
  - Device Input 2: Patient Video Analysis
  - Device Input 3: The answers to the Healthcare Provider Questionnaire
- A machine learning (ML) algorithm ('Algorithm') modeled after standard medical evaluation methodologies and drives the device outputs.
- Device outputs:

- ‘Positive for autism’
- ‘Negative for autism’
- ‘Indeterminate’

The MDDS components that are compatible with the SaMD components include the following:

- A caregiver facing mobile application, which provides Device Input 1;
- A video analyst system, which provides Device Input 2;
- A healthcare provider portal, which provides Device Input 3;
- Several supporting software and backend services and infrastructure, including privacy and security encryption and infrastructure in compliance with HIPAA and other best practices.

The subject of this submission is the inclusion of a Predetermined Change Control Plan (PCCP) that allows updates to the Canvas Dx model and performance thresholds.

INDICATIONS FOR USE
Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder (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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS
Cognoa, Inc. believes that the Canvas Dx device is substantially equivalent to the predicate devices based on the information summarized here:

	Subject Device: Canvas Dx	**Primary Predicate: Cognoa ASD Diagnosis Aid (DEN200069)**
Manufacturer	Cognoa, Inc.	Cognoa, Inc.
Regulation Number	21 CFR 882.1491	21 CFR 882.1491
Regulation Name	Pediatric Autism Spectrum Disorder diagnosis aid	Pediatric Autism Spectrum Disorder diagnosis aid
Regulatory Class	Class II	Class II
Product Code	QPF	QPF
Indications for Use	Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder (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.	The Cognoa ASD Diagnosis Aid is intended for use by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder (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.
Data Collection	▪ A caregiver facing mobile application, which provides Device Input 1 (Caregiver Questionnaire)	▪ A caregiver facing mobile application, which provides Device Input 1 (Caregiver Questionnaire)

	▪ A video analyst portal, which provides Device Input 2 (Patient Video Analysis) ▪ A healthcare provider portal, which provides Device Input 3 (HCP Questionnaire)	▪ A video analyst portal, which provides Device Input 2 (Patient Video Analysis) ▪ A healthcare provider portal, which provides Device Input 3 (HCP Questionnaire)
Outputs	▪ 'Positive for Autism' ▪ 'Negative for Autism' ▪ 'Indeterminate'	▪ 'Positive for ASD ▪ 'Negative for ASD ▪ 'No Result'
Software	Compliant to ISO 62304	Compliant to ISO 62304
Performance	The Canvas Dx performance thresholds will be updated based on improvements to the Algorithm per the terms of the PCCP presented in this 510(k).	The following thresholds are based on the initial performance of the device under the initial clinical validation study (prospective, double-blinded, single-arm) performed at 14 sites, compared to the clinical reference standard, in support of the DEN200069 submission. These values are based on review by 3 clinical specialists. ▪ **PPV:** 80.77% (CI: 70.27-88.82%) ▪ **NPV:** 98.25% (CI: 90.61-99.96%) ▪ **Determinate Rate (percent of users who received a positive or negative result):** 31.76% (CI: 63.58%-87.67%) ▪ **Sensitivity:** 98.44% (CI: 91.6%-99.96%) ▪ **Specificity:** 78.87% (CI: 67.56%-87.67%)

SUMMARY OF NON-CLINICAL TESTING
Testing was performed in accordance with IEC 62304:2006 to demonstrate safety based on current industry standards. The results of these tests indicate that Canvas Dx is substantially equivalent to the predicate device.

SUMMARY OF CLINICAL TESTING
Clinical testing was not performed in support of this submission

PREDETERMINED CHANGE CONTROL PLAN
Canvas Dx includes an authorized Predetermined Change Control Plan (PCCP) that allows for planned updates and modifications based on real-world data within the cleared indications for use. These modifications are related to:

1) Quantitative measures of machine learning-enabled device software functions (ML-DSF) performance specifications. This includes re-training the ML model based on new data within the intended use population from the same type and range of input signal. The re-training may result in internal decision trees with different weights or overall structure
2) Device inputs to the ML-DSF. This may involve expanding the algorithm to include new inputs of the same signal type.

The three modifications are summarized below.

1. Optimization of Decision Thresholds: Adjusting the predefined decision thresholds based on new data without modifying the existing model architecture, parameters, or structure. Optimizing decision thresholds can yield a higher determinate rate while maintaining or improving performance on PPV and NPV.

2. Model Retraining: Retraining the model with new data while maintaining the same set of input features and model architecture. Retraining may change feature weights and decision nodes based on the new data. Retraining the model based on new data enables the Device to adapt, improving generalizability and maintaining performance across evolving clinical populations.

3. Feature Addition: Adding neurodevelopmental/neurobehavioral features as inputs from the parent, video, or healthcare provider questionnaires, while maintaining the original set of input features and model architecture. Any new features will be limited to those that can be directly observed or reported through existing questionnaires and will not require additional separate testing or assessments. The addition of features may improve Device generalizability and performance, allowing for higher reliability and accuracy of the Device overall.

All modifications are subject to performance evaluation and update procedures, including software verification and validation. All modifications follow the same data management practices, as outlined in the PCCP Modification Protocol.

CONCLUSION

As the intended use and technological features of the subject Canvas Dx device have not changed since the original De Novo authorization of the Cognoa ASD Diagnosis Aid under DEN200069, it can be concluded that the subject Canvas Dx device does not raise new issues of safety or effectiveness compared to the predicate device. The Canvas Dx model and performance thresholds will be updated based on improvements to the Algorithm per the terms of the PCCP presented in this 510(k). Therefore, the subject Canvas Dx device is substantially equivalent to DEN200069.