June 2, 2021

Cognoa, Inc.
Sophie Dessalle
Vice President, Regulatory and Quality Affairs
2185 Park Blvd.
Palo Alto, CA 94306

Re: DEN200069
Trade/Device Name: Cognoa ASD Diagnosis Aid
Regulation Number: 21 CFR 882.1491
Regulation Name: Pediatric Autism Spectrum Disorder diagnosis aid
Regulatory Class: Class II
Product Code: QPF
Dated: October 31, 2020
Received: November 3, 2020

Dear Sophie Dessalle:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Cognoa ASD Diagnosis Aid, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> *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.*

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Cognoa ASD Diagnosis Aid, and substantially equivalent devices of this generic type, into Class II under the generic name pediatric Autism Spectrum Disorder diagnosis aid.

FDA identifies this generic type of device as:

> **Pediatric Autism Spectrum Disorder diagnosis aid**. A pediatric Autism Spectrum Disorder diagnosis aid is a prescription device that is intended for use as an aid in the diagnosis of Autism Spectrum Disorder in pediatric patients.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On November 3, 2020, FDA received your De Novo requesting classification of the Cognoa ASD Diagnosis Aid. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Cognoa ASD Diagnosis Aid into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Cognoa ASD Diagnosis Aid can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Device failure or incorrect analysis leading to: ● False positives resulting in inappropriate patient treatment and potentially delayed diagnosis of a non-ASD condition ● False negatives resulting in delayed diagnosis and patient treatment	Clinical performance testing Software verification, validation, and hazard analysis Labeling
Use error or misinterpretation of results resulting in a false positive or false negative	Usability assessment Labeling

In combination with the general controls of the FD&C Act, the pediatric Autism Spectrum Disorder diagnosis aid is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including an evaluation of sensitivity, specificity, positive predictive value, and negative predictive value using a reference method of diagnosis and assessment of patient behavioral symptomology.

(2) Software verification, validation, and hazard analysis must be provided. Software documentation must include a detailed, technical description of the algorithm(s) used to generate device output(s), and a cybersecurity assessment of the impact of threats and vulnerabilities on device functionality and user(s).

(3) Usability assessment must demonstrate that the intended user(s) can safely and correctly use the device.

(4) Labeling must include:
  (i) Instructions for use, including a detailed description of the device, compatibility information, and information to facilitate clinical interpretation of all device outputs;
  (ii) A summary of any clinical testing conducted to demonstrate how the device functions as an interpretation of patient behavioral symptomology associated with Autism Spectrum Disorder. The summary must include the following:
    (A) A description of each device output and clinical interpretation;
    (B) Any performance measures, including sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV);
    (C) A description of how the cut-off values used for categorical classification of diagnoses were determined; and
    (D) Any expected or observed adverse events and complications.
  (iii) A statement that the device is not intended for use as a stand-alone diagnostic.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the pediatric Autism Spectrum Disorder diagnosis aid they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for

combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act); 21 CFR 1000-1050.
A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Mohua Choudhury at 240-402-3095.

Sincerely,

Christopher Loftus -S
Digitally signed by Christopher Loftus -S
Date: 2021.06.02 07:20:02 -04'00'

Christopher Loftus, M.D.
Acting Director
OHT5: Office of Neurological
and Physical Medicine Devices
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