June 8, 2022

EarliTec Diagnostics, Inc.
℅ Sew-Wah Tay, Ph.D.
Regulatory Consultant
Libra Medical, Inc.
8401 73rd Ave N, Suite 63
Brooklyn Park, Minnesota 55428

Re: K213882
Trade/Device Name: EarliPoint System
Regulation Number: 21 CFR 882.1491
Regulation Name: Pediatric Autism Spectrum Disorder Diagnosis Aid
Regulatory Class: Class II
Product Code: QPF
Dated: December 28, 2021
Received: December 29, 2021

Dear Dr. Sew-Wah Tay:

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213882

Device Name
EarliPoint System

Indications for Use *(Describe)*
The EarliPoint System is indicated for use in specialized developmental disabilities centers as a tool to aid clinicians in the diagnosis and assessment of Autism Spectrum Disorder (ASD) for patients ages 16 months through 30 months.

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

1 SUBMITTER

Sponsor/Manufacturer
EarliTec Diagnostics, Inc.
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Correspondent
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Regulatory Consultant,
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Date prepared: March 17, 2022

2 DEVICE

Name of Device:	EarliPoint System
Common or Usual Name:	Pediatric Autism Spectrum Disorder diagnostic tool
Regulation Number:	21 CFR 882.1491
Regulatory Class:	II
Product Code:	QPF

3 PREDICATE DEVICE

Predicate Device: Cognoa ASD Diagnosis Aid (DEN200069)

Technological Reference: 2D VOG – Video-Oculography (K972243)

4 DEVICE DESCRIPTION

The EarliPoint System is a medical device for diagnosis of Autism Spectrum Disorder (ASD) in children.

EarliPoint System consists of the following:

- EarliPoint WebPortal to enter the patient information and for access to the patient

evaluation results,
- EarliPoint Device with eye-tracking capability captures the patient visual response to social information provided in the form of a series of age-appropriate videos
- Artificial intelligence software analyzes the eye-tracking data and provides a diagnosis for ASD.
- Eye-tracking data also outputs 3 indices (called EarliPoint Severity Indices) that proxy the ADOS-2 and Mullen validated ASD instruments
    - Social Disability Index correlates and proxies ADOS-2
    - Verbal Ability Index correlates and proxies the age equivalent Mullen Verbal Ability score
    - Non-verbal Ability Index correlates and proxies the age equivalent non-verbal Mullen Ability score

The eye-tracker used in the EarliPoint device has similar capability and specifications to the 2D VOG (K972243 – technological reference). The technical specifications of the 2D VOG are compared to the eye tracking component of EarliPoint.

Table 1. Eye Tracking Technical Specifications

Description	2D VOG (K972243)	EarliPoint Eye Tracking Sub-system
Wavelength	Near-Infrared Spectrum	Near-Infrared Spectrum
Intensity	Undefined but likely meets IEC/EN 62471	Conforms to safety limit for continue use per IEC/EN 62471 (Photobiological safety of lamps/lamp system)
Light source	IR LED	IR LED
Duration of Use/Exposure	~15 minutes	~15 minutes
Accuracy/Precision for intended use (gaze position)	Unknown	0.5°
Recording Measurement	2D Eye Movements	2D Eye Movements
Video Hardware	Video Camera	Video Camera
Mounting Hardware	Mobile eye tracking (Face Mask)	Remote eye-tracking system (Display Screen)

Description	2D VOG (K972243)	EarliPoint Eye Tracking Sub-system
Processor Hardware	Personal computer	Personal computer
Sampling Rate	Undefined	120 Hz

5 INDICATIONS FOR USE

The EarliPoint System is indicated for use in specialized developmental disabilities centers as a tool to aid clinicians in the diagnosis and assessment of ASD patients ages 16 months through 30 months.

6 PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

6.1 Mechanical/electrical safety and electromagnetic compatibility (EMC)

Mechanical/electrical safety and EMC testing were conducted on the EarliPoint device consisting of the patient console and the operator console for patient behavioral tracking. The EarliPoint device is classified as Class I for protection against electric shock with Type B applied part and is intended for continuous mode of operation. Compliance testing shows that the EarliPoint device complies with all the applicable tests of IEC 60601-1 standard for mechanical/electrical safety and the IEC 60601-1-2 standard for EMC.

6.2 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "minor" level of concern as a failure or latent flaw in the software is unlikely to result in injury.

6.3 Clinical Studies

The safety and effectiveness of the EarliPoint System in diagnosing the presence ASD was evaluated in a pivotal study where patients were diagnosed by the device as well and expert clinicians (reference standard).

In addition, a repeatability and reproducibility study showed that the EarliPoint diagnosis is reliable and consistent. The pivotal study showed that the device is safe and effective as a tool to assist clinician in diagnosing young children for ASD.

6.3.1 Pivotal Study Design

The pivotal study was a prospective, double-blind, multi-center, within-subject comparison where 500 patients from six sites in the United States were enrolled, of which 475 were evaluable for primary and secondary endpoint analysis and 25 patients had missing data of the device or the control diagnosis (standard of care).

All patients were evaluated for ASD by both the EarliPoint system and by expert clinician diagnosis (current best practice for diagnosis of ASD) to evaluate the sensitivity and specificity of the EarliPoint System diagnosis relative to the expert clinical diagnosis. The study also correlated the three EarliPoint Severity Indices of social disability, verbal ability and nonverbal ability against the corresponding expert clinical instruments of ADOS-2 and Mullen.

The pivotal study showed that the EarliPoint device was safe and effective in the diagnosis of ASD in children. There was no reported serious adverse event related to the use of the EarliPoint system and, like the CanvasDx device study, there was evidence of EarliPoint device performance differences across subjects based on sex, race/ethnicity.

When compared to the predicate, CanvasDx, the sensitivity and specificity of the EarliPoint device are higher than the CanvasDx and hence the two devices are substantially equivalent.

Population	Sensitivity Mean (n/N) 95% CI	Specificity Mean (n/N) 95% CI
CanvasDx (mITD) N=425	51.6% (63/122) 42.8% - 60.5%	18.5% (56/303) 14.3% - 23.3%)
EarliPoint (mITD) N=475	71% (157/221) 64.6% - 76.9%	80.7% (205/254) 75.3% - 85.4%
EarliPoint CertainDx (Clinicians are Certain of Diagnosis only) N=335	78.0% (117/150) 70.5%, 84.3%	85.4% (158/185) 79.5% - 90.2%

The primary effectiveness endpoint was compared to the gold standard of the expert clinician diagnosis. Three populations were evaluated for the primary endpoint: mITD (n=475, all patients with evaluable data), Certain Dx Population (n=335, patients with expert clinician diagnosis with certainty rating > 80%), and Uncertain Dx Population (n=140, patients with expert clinician diagnosis with certainty rating ≤ 80%). As expected, the best results were obtained when the ground truth (clinicians' reference diagnoses) were more certain.

For the subgroup of Uncertain Dx population, given the uncertain nature of the expert diagnosis, the EarliPoint system showed low specificity and sensitivity with mean specificity of 68.1% (p=0.69) and mean sensitivity of 56.3% (p=1.00).

6.3.2 Repeatability and Reproducibility Study

In the EarliPoint repeatability and reproducibility study, the variance attributable to the device is 6.18 % repeatability and 0% for reproducibility assuming no subject and device interaction. Majority of the variance is a result of subject-to-subject variability.

7 PREDICATE COMPARISON

7.1 Intended Use Comparison

The EarliPoint system has the same intended use as the Cognoa ASD Diagnosis Aid (DEN200069). Both are intended for non-invasive objective evaluation of the ASD status of a child by using software to analyze the child's behavior in response to external stimuli. Both are intended for use in to evaluate young children.

While the indication for use of the devices differs slightly, the intended use is the same. The EarliPoint system diagnostic tool outputs definite diagnosis of positive ASD or negative ASD for each and every patient while the CanvasDx device outputs an actual diagnosis of ASD or non-ASD in only 32% of the time. In 68% of the time, the CanvasDx output an indeterminate diagnosis. Hence the CanvasDx is indicated as a screening aid for diagnosis of ASD. Results from both devices are intended to be presented to the patient's family by a trained clinician.

While the indications for use statements are not identical, we believe that the intended use is substantially equivalent for the purpose of the device classification of the EarliPoint system as a Class II device. Hence the EarliPoint System met the first criteria for substantial equivalence

7.2 Technological Characteristics Comparison With The Predicate CanvasDx Device

Description	Subject Device: EarliPoint System	Predicate Device: Cognoa ASD Diagnosis Aid (DEN200069)	Technological Reference Sensomotoric Eye Tracker (K972243)
Data collection	Patient console with eye-tracking technology for data collection and software analysis for diagnosis of ASD.	Data collected using normal commercially available camera to videotaped behavior	Similar eye-tracking technology for data collection
ASD diagnosis	Use software algorithm to analyze the eye tracking data and compare it to data model of normative data for diagnosis	Software analysis of video, behavior assessments questionnaires (parent, video-based expert, and healthcare professional) to generate assessment of ASD.	NA
Electrical safety testing	Meets electrical safety standards per IEC 60601-1 2005:2012	Not applicable as this is software as a medical device	Met all electrical and LED safety testing
Software	Compliant to ISO 62304	Compliant to ISO 62304	NA
Clinical performance data for ASD	Pivotal data available to show safety and effectiveness	Pivotal data available to show safety and effectiveness	NA
Risk level of the device	Low risk device, non-invasive	Low risk device	Low risk device

The principle technological characteristic for both the subject and predicate device (CanvasDx) is digitizing the patient's reaction to social stimuli in the form of video and using software to analyze the child's reaction for the evaluation of ASD. Both devices are non-invasive and are of low risk. The eye-tracker is technological similar to the 2D VOG eye-tracker which have

decades of safe use so there are no new safety questions.
The EarliPoint device analyzes the patient reaction to social stimuli by tracking the patient's eye movement when stimulated by a series of videos of social scenes while the predicate analyzes the videos of the patient's reaction when placed in a socially stimulating setting. The CanvasDx device analyzes the patient reaction to social stimuli by taking a video of the patient's and analyzing the video in combination with assessments from the caregiver and primary care giver after digitizing the responses.

Both devices use artificial intelligence software to analyze the patient's reaction to provide an ASD diagnosis or assist in the diagnosis for ASD.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Collection of digital information of patient's reaction when stimulated socially.
- Software analysis of patient physical reactions for evaluation of ASD.

Scientific data in the form of clinical performances of the device show that any technological differences between the subject and predicate devices do not raise new or different concerns of safety and efficacy.

7.3 Substantial Equivalence Conclusion

Based on the same intended use, technological characteristics, and the summary of data submitted, the EarliPoint device is found to be substantially equivalent to the predicated device. Safety and performance test data including bench testing to IEC 60601-1 (2012) and comprehensive assessment including clinical data, demonstrated the device safety and effectiveness as intended without raising new and different questions of safety and effectiveness.