June 29, 2023

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

Re: K230337
Trade/Device Name: EarliPoint
Regulation Number: 21 CFR 882.1491
Regulation Name: Pediatric Autism Spectrum Disorder Diagnosis Aid
Regulatory Class: Class II
Product Code: QPF
Dated: May 31, 2023
Received: June 1, 2023

Dear 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,

Patrick Antkowiak -S

for
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

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 ASD 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 ADMINISTRATIVE INFORMATION

510(k) Submission Type:	Traditional 510(k)
Device Type (Common Name):	Pediatric Autism Spectrum Disorder Diagnostic Tool
Device Classification Name	Pediatric Autism Spectrum Disorder Diagnostic Aid
Device Trade Name	EarliPoint System
Predicate Device Name	EarliPoint System (K213882)
510(k) Submitter:	Thomas Ressemann, CEO EarliTec Diagnostics, Inc. 755 Commerce Drive, Suite 700 Decatur, GA 30030 Tel:+1-320-267-7266 Email: tressemann@earlitecdx.com
Primary Correspondent:	Sew-Wah Tay Regulatory Consultant Libra Medical, Inc. Tel: 612-801-6782 Email: swtay@libramed.com
Classification Regulation:	21 CFR 882.1491
Class:	II
Panel:	Neurology Devices Panel
Product Code:	QPF

2 510(K) TYPE AND REASON FOR SUBMISSION

This 510(k) is submitted as a traditional 510(k) to obtain marketing clearance for the modified EarliPoint System, a modification to the form factor of the device to improve usability and portability.

3 INTENDED USE

The EarliPoint System is intended for use by healthcare providers to objectively diagnose and assess children for ASD using software algorithm to analyze a child's response to an external stimulus in the form of videos.

4 INDICATION 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.

5 PREDICATE DEVICE

The predicate device is the EarliPoint System cleared under 510(k) K213882. Both devices have the same intended use as an aid to diagnose and assess the presence of autism spectrum disorders (ASD) using a proprietary algorithm based on the looking behavior of the patient.

6 DEVICE DESCRIPTION

The device is a more compact version of the predicate device but otherwise has similar functions and features. The system uses an eye tracker to capture the patient's looking behavior while viewing a series of videos. The system then remotely analyzes the looking behavior data using software and outputs a diagnosis of the patient's ASD status and assesses the symptoms associated with ASD.

The system has two modules:

EarliPoint System consists of the following:

- Eye-tracking module and a separate Operator Module that can control the Eye-tracking module remotely. The patient sits on a chair and the Eye-tracking module is adjusted by the operator such that the patient's eyes are within the specification of the eye tracking window
- Eye-tracking module captures the patient visual response to social information provided in the form of a series of age-appropriate videos
- Operator's module is used to initiate and monitors the session remotely
- WebPortal securely stores all patient information, analyzes the eye tracking data, and outputs the results. Users can retrieve the results directly from the web-portal.
- Artificial intelligence software analyzes the eye-tracking data and provides a diagnosis for ASD. In addition, it 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 as the eye tracker used in the predicate device.

Description	EarliPoint Eye Tracking Specifications
Wavelength	Near-Infrared Spectrum
Intensity	Conforms to safety limit for continue use per IEC/EN 62471 (Photobiological safety of lamps/lamp system)
Light source	IR LED
Duration of Use/Exposure	~15 minutes

Description	EarliPoint Eye Tracking Specifications
Accuracy/Precision for intended use (gaze position)	0.5°
Recording Measurement	2D Eye Movements
Video Hardware	Video Camera
Mounting Hardware	Remote eye-tracking system (Display Screen)
Processor Hardware	Personal computer
Sampling Rate	120 Hz

6.1 PERFORMANCE TESTING

The basis of the substantial equivalence between the device and its predicate is the bench performance tests. Both devices meet the electrical safety standards and both software were designed and tested per IEC 62304.

To ensure that the device is substantially equivalent, the new eye tracker is verified to meet the predicate eye tracker requirement specifications for the device. In addition, the performance of the eye trackers used in the predicate device and the current device were compared directly using adult participants for identifications of blinks, saccades, non-missing samples, and fixation accuracy. The eye-tracker tests demonstrated that both the new eye tracker and the predicate eye tracker meet the requirements for the eye tracker. Hence the two eye trackers are functionally equivalent and interchangeable.

The second performance test is to ensure that the analysis algorithm is equivalent and will output the same results as the original analysis algorithm. To demonstrate the equivalency of the software, the collected session data from the pivotal clinical study were processed through the current software. Each ASD diagnoses and Indices of Social Disability, Verbal Ability, and Nonverbal Ability provided by predicate and the current device were compared and found to be the same, demonstrating the equivalency of the current device's data analysis software to the predicate data analysis software.

6.2 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.

6.3 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.

6.4 CLINICAL STUDIES

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

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.

Population	Sensitivity Mean (n/N) 95% CI	Specificity Mean (n/N) 95% CI
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%

7 SUBSTANTIAL EQUIVALENT COMPARISON

Device Characteristic	EarliPoint System K213882	Updated EarliPoint System Candidate Device
Intended Use	The EarliPoint System is intended for use by healthcare providers to objectively diagnose and assess children for ASD using software algorithm to analyze a child's response to an external stimulus in the form of videos.	The EarliPoint System is intended for use by healthcare providers to objectively diagnose and assess children for ASD using software algorithm to analyze a child's response to an external stimulus in the form of videos.
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.	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.
Prescription Use	Yes	Yes
Product Code and	QPF	QPF
Regulation Number	882.1491	882.1491
Device Components	Patient console with eye-tracking technology for data collection and software analysis for diagnosis of ASD. Both patient and Operator screens are controlled by the same computer.	Similar components as EarliPoint System with a smaller device form factor. Patient and Operator screens are separate computer devices connected indirectly through the web-portal
ASD Diagnosis	Use software algorithm to analyze the eye tracking data for ASD diagnosis ad assessment	No change. Same software algorithm
Electrical Safety Testing	Meets electrical safety standards per: • IEC 60601-1:2005/AMD1:2012/AMD2:2020 • IEC 60601-1-2:2014/AMD1:2020	Meets electrical safety standards per: • IEC 60601-1:2005/AMD1:2012/AMD2:2020 • IEC 60601-1-2:2014/AMD1:2020
Software	Compliant to ISO 62304	Compliant to ISO 62304
Clinical data	Pivotal data shows safety and effectiveness. Data is analyzed using the Data Analysis module.	Data Analysis software is verified so that the output is the same as the predicate device.
Risk level of the device	Low risk device, non-invasive	Low risk device, non-invasive

7.1 CONCLUSION

Both devices have the same intended use and the same indication for use. The technological differences between the two devices are minor and verified via bench testing to be equivalent. The conclusions drawn from the nonclinical demonstrate that the device is as safe, as effective, and performs as well as the legally marketed device. Hence, the subject device is substantially equivalent to the predicate device.