March 26, 2025

EarliTec Diagnostics, Inc.
% Amy Wolbeck
Regulatory Consultant
RQM+
2790 Mosside Blvd.
Monroeville, Pennsylvania 15146

Re: K243891
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: February 21, 2025
Received: February 24, 2025

Dear Amy Wolbeck:

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.

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)*

K243891

Device Name

EarliPoint

Indications for Use *(Describe)*

The EarliPoint System device is indicated as a tool to aid qualified clinicians in the diagnosis and assessment of Autism Spectrum Disorder (ASD) in children ages 16 months through 30 months, who are at risk based on concerns identified by a parent, caregiver, or healthcare provider.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

510(k) Information	
510(k) Number	
510(k) Type	Special 510(k)
Date Prepared	18 December 2024
Submitter Information	
510(k) Submitter:	Ryan Bormann, Director of Quality and Operations EarliTec Diagnostics, Inc. 13895 Industrial Park Blvd, Suite 140 Tel:+1-833-504-9937 Email: rbormann@earlitecdx.com
Primary Correspondent:	Amy Wolbeck Regulatory Consultant RQM+ 2790 Mosside Blvd. Monroeville, PA 15146 Tel:+1-707-291-3457 Email: awolbeck@rqmplus.com
EarliPoint System Device Information	
Trader Name (Common Name):	EarliPoint System Device
Device Classification Name	Pediatric Autism Spectrum Disorder Diagnostic Aid
Classification Regulation:	21 CFR 882.1491
Class:	II
Panel:	Neurology Devices Panel
Product Code:	QPF
Predicate Device	EarliPoint System K230337
Device Description	The EarliPoint 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 associated developmental delay indicies. The EarliPoint System device 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

	developmental delay 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
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.
Indications for Use	The EarliPoint System device is indicated as a tool to aid qualified clinicians in the diagnosis and assessment of Autism Spectrum Disorder (ASD) in children ages 16 months through 30 months, who are at risk based on concerns identified by a parent, caregiver, or healthcare provider.
EarliPoint System Nonclinical and Clinical Data (unchanged from predicate device)	
Performance Testing	EarliPoint was verified to meet the electrical safety standards and the software were designed and tested per IEC 62304.
Mechanical/Electrical Safety and Electromagnetic Compatibility (EMC)	Mechanical/electrical safety and EMC testing were conducted on the EarliPoint device. 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.
Software Verification and Validation	Software verification and validation testing were successfully completed.
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%

SUBSTANTIAL EQUIVALENT COMPARISON

Device Characteristic	Predicate Device K230337 EarliPoint System	Subject Device EarliPoint System
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.	Same as predicate
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 device is indicated as a tool to aid qualified clinicians in the diagnosis and assessment of Autism Spectrum Disorder (ASD) in children ages 16 months through 30 months, who are at risk based on concerns identified by a parent, caregiver, or healthcare provider.
Prescription Use	Yes	Same as predicate
Product Code and	QPF	Same as predicate
Regulation Number	882.1491	Same as predicate
Device Components	• 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 monitor the session remotely	Same as predicate

Device Characteristic	Predicate Device K230337 EarliPoint System	Subject Device EarliPoint System
	• 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. • Software analyzes the eye-tracking data and provides a diagnosis for ASD. In addition, it also outputs 3 developmental delay indices (called EarliPoint Severity Indices) that proxy the ADOS-2 and Mullen validated ASD instruments	
ASD Diagnosis	Use software algorithm to analyze the eye tracking data for ASD diagnosis ad assessment	Same as predicate
Electrical Safety Testing	Meets electrical safety standards per: • IEC 60601-1:2005/AMD1:2012/AMD2:2020 • IEC 60601-1-2:2014/AMD1:2020	Same as predicate
Software	Compliant to ISO 62304	Same as predicate
Clinical data	Pivotal trials provide safety and effectiveness data.	Same as predicate
Risk level of the device	Low risk device, non-invasive	Same as predicate

CONCLUSION

Both devices have the same intended use and technological characteristics. The clarifications made to the indications for use statement do not impact the safety and effectiveness of the device. The conclusions drawn from the nonclinical and clinical studies have not been impacted by this clarification in the indications for use statement. Hence, the subject device is substantially equivalent to the predicate device.