March 5, 2026

Earlitec Diagnostics
℅ Amy Wolbeck
Regulatory Consultant
Rqm+
2790 Mosside Blvd.
Pittsburgh, Pennsylvania 15146

Re: K253442
Trade/Device Name: EarliPoint Assessment
Regulation Number: 21 CFR 882.1491
Regulation Name: Pediatric Autism Spectrum Disorder Diagnosis Aid
Regulatory Class: Class II
Product Code: QPF
Dated: February 3, 2026
Received: February 3, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K253442

Device Name
EarliPoint Assessment

Indications for Use *(Describe)*
The EarliPoint Assessment 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 95 months (7 years), 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.

510(K) SUMMARY - K253442

510(k) Information	
510(k) Number	K253442
510(k) Type	Traditional 510(k)
Date Prepared	3 February 2026
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+ 5000 Centregreen Way, Suite 100 Cary, NC 27513 Tel:+1-707-291-3457 Email: awolbeck@rqmplus.com
EarliPoint System Device Information	
Trader Name (Common Name):	EarliPoint Assessment
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 K243891
Device Description	The EarliPoint assessment uses an eye tracker to measure 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 indices. 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.

	• 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 validated ASD instruments
Intended Use	Intended for use as an aid in the diagnosis of Autism Spectrum Disorder in pediatric patients
Indications for Use	The EarliPoint Assessment 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 95 months (7 years), who are at risk based on concerns identified by a parent, caregiver, or healthcare provider.
EarliPoint System Nonclinical 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.
EarliPoint System Software Testing	
Software Verification and Validation	Software verification and validation testing were successfully completed.
EarliPoint System Clinical Testing for Expanded Age Range	
Clinical Studies	The safety and effectiveness of the EarliPoint Assessment in collecting eye-tracking data and analyzing the data for diagnosing the presence of ASD was evaluated in a pivotal study in children ages 31 months to 7 years (<96 months). 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 validated ASD instruments. The EarliPoint evaluation was safe (no serious adverse events or device-related adverse events) and effective: it had strong sensitivity and specificity in comparison with Reference Standard categorical diagnoses (sensitivity 77.1% and specificity 78.6%) and has robust convergent validity in comparison with Reference Standard assessments of social disability, verbal ability, and nonverbal cognitive ability made by highly trained experts at leading expert centers. These results augment EarliPoint's

	previously cleared indication for use in children ages 16 through 30 months.

Comparison to Predicate Device

Intended Use/Indications for Use Comparison

The subject device and the predicate have the same intended use. Specifically, both devices are intended for use as an aid in the diagnosis of Autism Spectrum Disorder (ASD) in pediatric patients. The subject device and the predicate have the same indications for use with the exception being the subject device expands the age range from 16-30 months to 31-95 months of age. Clinical testing conducted in the expanded age range demonstrated that the device is as safe and effective as the predicate. The expanded age range does not raise new questions of safety or effectiveness. Clinical data has been provided to support the modified indications for use.

Technological Characteristics

The subject device has the same technological characteristics as the predicate as outlined in the table below.

Substantial Equivalent Comparison

Device Characteristic	Predicate Device K243891 EarliPoint System	Subject Device K253442 EarliPoint Assessment
Intended Use	Intended for use as an aid in the diagnosis of Autism Spectrum Disorder in pediatric patients	Same as predicate
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.	The EarliPoint Assessment 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 95 months (7 years), 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 • 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.	Same as predicate, except for the number of device output labels (*positive*, *negative*, and *borderline* for the subject device vs. only *positive* and *negative* for the predicate). This does not adversely impact the safety and effectiveness of the subject device as compared to the predicate.

Device Characteristic	Predicate Device K243891 EarliPoint System	Subject Device K253442 EarliPoint Assessment
	• Software analyzes the eye-tracking data and provides diagnostic scores with labels to aid in ASD diagnosis. In addition, it also outputs 3 developmental delay indices (called EarliPoint Severity Indices) that proxy validated ASD instruments	
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

Clinical Studies

The safety and effectiveness of the EarliPoint System in diagnosing the presence of ASD was evaluated in 2 prospective, double-blind, multi-center, within-subject comparison, US, pivotal studies. The first study evaluated 16-30-month-old children and supported the original 510(k) clearance of the device (K213882). The second study evaluated 31 to <96 month-old children. All study subjects in both clinical studies 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. These studies 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/DAS-II.

As autism is defined as a spectrum disorder, the distinction between autism spectrum disorder (ASD) and non-ASD presentations is at times nuanced and clinicians frequently encounter challenges in delineating clear boundaries between individuals with ASD and individuals who do not have ASD. The subject device includes implementation of a borderline range for EarliPoint diagnostic scores close to the threshold delineating ASD-positive from ASD-Negative, as such borderline cases may require additional observation from a clinician to determine the appropriate diagnosis.

EarliPoint outputs a Diagnostic Index Score for each session, typically ranging from -30 to +30. Based on this score, EarliPoint provides one of the following diagnoses:

- Consistent with autism - Scores ≤0
- Borderline Range - Scores >0 and ≤3
- Not Consistent with autism - Scores >3

Scores between 0 and 3 are considered borderline. Further assessment is advised to determine presence or absence of autism.

Clinical Study Safety and Effectiveness

The pivotal studies 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. When compared to the predicate, the sensitivity and specificity of the EarliPoint device was found to be substantially equivalent to the subject device.

The data from the original clinical study for the 16-30-month-old children is provided in the table below under the predicate device column. As the original device did not include a borderline output, the clinical trial data was reanalyzed with the implementation of the borderline range in the table below under the subject device column, EarliPoint System 16-30 months. Data from the second clinical study evaluating 31 to <96 month old children is provided in the table below EarliPoint System 31 to <96 months. The last column in the table below provides the data from the 2 clinical studies, EarliPoint System 16 to <96 months.

	Predicate Device (K243891)	Subject Device			Comparison
Performance Measure	**EarliPoint System 16-30 months**	**EarliPoint System 16-30 months**	**EarliPoint System 31 to <96 months**	**EarliPoint System 16 to <96 months**	
Sensitivity	78.0% (70.5 - 84.3) 117/150	84.8% (77.7 - 90.3) 117/138	77.1% (70.7 - 82.7) 155/201	80.2% (75.6 - 84.3) 272/339	Substantially Equivalent
Specificity	85.4% (79.5 - 90.2) 158/185	84.0% (77.6 - 89.2) 142/169	78.6% (71.6 - 84.5) 132/168	81.3% (76.7 - 85.3) 274/337	Substantially Equivalent
Positive Predictive Value	81.3% (73.9 - 87.3) 117/144	81.3% (73.9 - 87.3) 117/144	81.2% (74.9 - 86.4) 155/191	81.2% (76.6 - 85.2) 272/335	Substantially Equivalent
Negative Predictive Value	82.7% (76.6 - 87.8) 158/191	87.1% (81.0 - 91.8) 142/163	74.2% (67.1 - 80.4) 132/178	80.4% (75.7 - 84.4) 274/341	Substantially Equivalent
Accuracy	82.1% (77.6 - 86.0) 275/335	84.4% (79.8 - 88.2) 259/307	77.8% (73.2 - 81.9) 287/369	80.8% (77.6 - 83.7) 546/676	Substantially Equivalent

Each cell gives the performance measure as percentage with corresponding two-sided 95% confidence interval, together with participant counts for each measure.

Note: All confidence intervals (CI) calculated as two-sided 95% CI, estimated using the Clopper-Pearson (exact) approach.

Reference Standard Clinical Uncertainty

As noted in the existing clinical literature in autism (McDonnell et al, *JADD*, 2019 and Klaiman et al, *JADD*, 2024), current best practice diagnosis of autism is challenging, and clinicians are sometimes less than fully certain that their own diagnoses are accurate. McDonnell et al found that clinicians were only fully certain of the accuracy of their diagnoses in 60% of cases (40% uncertain), while Klaiman et al documented 29.5% uncertainty.

In the EarliPoint studies there were 252 uncertain diagnoses out of a total of 1064 subjects (23.7%), which is less than rates reported in the literature, evidence of the fact that the EarliPoint clinical trial procedures worked effectively to reduce and minimize, to the extent possible, clinician uncertainty in the reference standard diagnosis.

Stratum-Specific Likelihood Ratios (SSLR)

The Stratum-Specific Likelihood Ratios (SSLR) provided in demonstrates that participants who receive EarliPoint scores in the Borderline range are meaningfully distinct from those who receive scores in the ASD (positive) or Non-ASD (negative) range. The non-overlapping SSLR confidence intervals demonstrate that the Borderline group does not represent a probabilistic blend of positive and negative outcomes, but instead constitutes a distinct profile. This separation supports EarliPoint's ability to identify Borderline cases with a meaningful degree of diagnostic specificity.

In practice, this supports the clinical interpretation of a Borderline EarliPoint result as an intermediate risk category. These cases warrant closer clinical review, integration with additional clinical information, and additional evaluation, rather than being interpreted as clearly positive or negative.

Stratum-Specific Likelihood Ratios for Clinical Trial Borderline Range			
Performance Measure	**EarliPoint System 16-30 months (K243891)**	**EarliPoint System 31 - <96 months (K253442)**	**Entire age range 16 - <96 months**
Positive (ASD) SSLR (95% CI)	5.34 (3.73, 7.65)	4.11 (3.01, 5.62)	4.58 (3.61, 5.81)
Borderline Range SSLR (95% CI)	0.92 (0.45, 1.89)	0.63 (0.45, 0.89)	0.72 (0.53, 0.99)
Negative (Non-ASD) SSLR (95% CI)	0.18 (0.12, 0.27)	0.18 (0.12, 0.27)	0.26 (0.21, 0.33)
[1] The 95% CI for SSLR is based on the formula introduced by Peirce and Cornell (1993). [2] Positive: EarliPoint diagnostic scores ≤ 0; Borderline: EarliPoint diagnostic scores > 0 and ≤ 3; Negative: EarliPoint diagnostic scores > 3.			

Performance Results with and without Borderline Range

Ages 16-30 Months are captured in Table 5-1 below. All certain diagnoses by clinical reference standard (uncertain diagnoses were not included in performance analysis, n=140 for 16-30 months):

Table 5-1: Certain Diagnoses by Reference Standard (16-30 Months)		
Population (16 to 30 months)	**Sensitivity**	**Specificity**
EarliPoint, borderline range not implemented, predicate K243891 N=335	78.0% (117/150) 95% CI: 70.7%, 83.9%	85.4% (158/185) 95% CI: 79.5%, 90.2%
EarliPoint, with borderline range implemented as separate output*, predicate K243891 N=307	84.8% (117/138) 95% CI: 77.7%, 90.3%	84.0% (142/169) 95% CI: 77.6%, 89.2%

* Borderline cases were not included in sensitivity/specificity calculations given the device's intended use

Ages 31 to <96 Months are captured in Table 5-2 below. All certain diagnoses by clinical reference standard (uncertain diagnoses were not included in performance analysis, n=112 for 31 to <96 months):

Table 5-2 Certain Diagnoses by Reference Standard (31 - <96 Months)		
Population (31 to <96 months)	**Sensitivity**	**Specificity**
EarliPoint, borderline range considered ASD-negative* N=477	63.5% (155/244) 95% CI: 57.1%, 69.6%	84.5% (197/233) 95% CI: 79.3%, 88.9%
EarliPoint, with borderline range implemented as a separate output** N=369	77.1% (155/201) 95% CI: 70.7%, 82.7%	78.6% (132/168) 95% CI: 71.6%, 84.5%

* In this row, borderline cases were considered ASD-negative, consistent with the predicate device (borderline range not implemented). However, in the intended use of EarliPoint, scores in the borderline range, close to the threshold delineating ASD-positive from ASD-Negative (>0 and ≤3), will not be labeled as either "ASD-positive" or "ASD-negative". These patients who fall in the borderline range have results that are not clearly consistent with either "ASD-positive" or "ASD-negative" and may require additional observation from a clinician to determine the appropriate diagnosis.

** Borderline cases were not included in sensitivity/specificity calculations given the device's intended use

Ages 16 to <96 Months are captured in Table 5-3 below. All certain diagnoses by clinical reference standard (uncertain diagnoses were not included in performance analysis, n=252 for 16 to <96 months):

Table 5-3 Certain Diagnoses by Reference Standard (16 - <96 Months)		
Population (16 to <96 months)	**Sensitivity**	**Specificity**
EarliPoint, borderline range considered ASD-negative* N=812	69.0% (272/394) 95% CI: 64.2%, 73.6%	84.9% (355/418) 95% CI: 81.1%, 88.2%
EarliPoint, with borderline range implemented as separate output** N=676	80.2% (272/339) 95% CI: 75.6%, 84.3%	81.3% (274/337) 95% CI: 76.7%, 85.3%

* In this row, borderline cases were considered ASD-negative, consistent with the predicate device (borderline range not implemented). However, in the intended use of EarliPoint, scores in the borderline range, close to the threshold delineating ASD-positive from ASD-Negative (>0 and ≤3), will not be labeled as either "ASD-positive" or "ASD-negative". These patients who fall in the borderline range have results that are not clearly consistent with either "ASD-positive" or "ASD-negative" and may require additional observation from a clinician to determine the appropriate diagnosis.

** Borderline cases were not included in sensitivity/specificity calculations given the device's intended use

Note: All confidence intervals (CI) calculated as two-sided 95% CI, estimated using the Clopper-Pearson (exact) approach.

CONCLUSION

Both devices have the same intended use and technological characteristics. The modification to the indications for use statement of the subject device is to expand the age range for use with children through 95 months of age. Clinical data from the expanded age range demonstrates the safety and effectiveness of the device without raising new or different questions of safety and effectiveness. The conclusions drawn from the nonclinical, software testing and clinical studies support the safety and effectiveness of the device. Hence, the subject device is substantially equivalent to the predicate device.