October 16, 2024

Abbott Laboratories Diagnostics Division
Bryant Tate
Manager of Regulatory Affairs
1915 Hurd Drive, Department RA11, Building LC 8 - 4th Floor MS 8-9
Irving, Texas 75038

Re: K240468
Trade/Device Name: Alkaline Phosphatase
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline Phosphatase Or Isoenzymes Test System
Regulatory Class: Class II
Product Code: CJE
Dated: September 16, 2024
Received: September 16, 2024

Dear Bryant Tate:

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 and Part 809); 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,

Paula V. Caposino -S

Paula Caposino, Ph.D.
Deputy Director
Division of Chemistry and
Toxicology Devices
OHT7: Office of In Vitro Diagnostics
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.

510(k) Number *(if known)*
K240468

Device Name
Alkaline Phosphatase

Indications for Use *(Describe)*
The Alkaline Phosphatase assay is used for the quantitation of alkaline phosphatase in human serum or plasma.

Measurements of alkaline phosphatase or its isoenzymes are to be used as an aid in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

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

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

I. 510(k) Number

K240468

II. Applicant Name

Abbott Laboratories Diagnostics Division
1915 Hurd Drive
Department RA11, Building LC 8 - 4th Floor MS 8-9
Irving, TX 75038
United States

Primary contact person for all communications:

Bryant Tate, Manager of Regulatory Affairs
Abbott Laboratories, Core Diagnostics
bryant.tate@abbott.com
Primary Phone (214) 862-6620
Alternate Phone (972) 518-6260

Secondary contact person for all communications:

Jacek Gorzowski, Director of Regulatory Affairs
Abbott Laboratories, Core Diagnostics
jacek.gorzowski@abbott.com
Phone (224) 668-1740

Date Summary Prepared: October 16, 2024

III. Device Name

Device Trade Name: Alkaline Phosphatase

Common Name: Alkaline phosphatase or isoenzymes test system
Classification Name: Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes
Governing Regulation Number: 21 CFR §862.1050
Product Code: CJE

IV. Legally Marketed Predicate Device

Predicate Number: K023807
Predicate Trade Name: Alkaline Phosphatase
Product Code: CJE

V. Device Description Summary

The Alkaline Phosphatase assay is an automated clinical chemistry assay.

Alkaline phosphatase in the sample catalyzes the hydrolysis of colorless p-nitrophenyl phosphate (p-NPP) to give p-nitrophenol and inorganic phosphate. At the pH of the assay (alkaline), the p-nitrophenol is in the yellow phenoxide form. The rate of absorbance increase at 404 nm is directly proportional to the alkaline phosphatase activity in the sample. Optimized concentrations of zinc and magnesium ions are present to activate the alkaline phosphatase in the sample.

The kit configurations of the Alkaline Phosphatase reagent kits are described below.

	List Number	
	7D55-22	**7D55-32**
Estimated tests per kit	1,500*	11,358*
Reagent 1 (R1)	5 x 21 mL	10 x 84 mL
Reagent 2 (R2)	5 x 9 mL	10 x 26 mL

*Calculation is based on the minimum reagent fill volume per kit.

Reactive Ingredients	**Concentration**
R1	
2-amino-2-methylpropanol	> 1.2 mol/L
Magnesium	> 7.2 mmol/L
Zinc sulfate	> 3.6 mmol/L
HEDTA	> 7.2 mmol/L
R2	
4-nitrophenyl phosphate	> 171.6 mmol/L

VI. Intended Use/Indications for Use

The Alkaline Phosphatase assay is used for the quantitation of alkaline phosphatase in human serum or plasma.

Measurements of alkaline phosphatase or its isoenzymes are to be used as an aid in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

VII. Technological Comparison

The similarities and differences between the subject device (Alkaline Phosphatase) and the predicate device (Alkaline Phosphatase [k023807]) are presented in the following table.

Characteristics	Subject Device: Alkaline Phosphatase	Cleared Predicate Device: Alkaline Phosphatase Special 510(k) k023807
General Device Characteristic Similarities		
Platform	ARCHITECT c8000 instrument	Same
Intended Use and Indications for Use	The Alkaline Phosphatase assay is used for the quantitation of alkaline phosphatase in human serum or plasma.	Same
Methodology	Para-nitrophenyl phosphate	Same
Specimen Type	Human serum or plasma	Same
Assay Principle / Principle of Procedure	Several substrates have been used to measure alkaline phosphatase activity such as glycerophosphate,[1] phenyl phosphate,[1] and p-nitrophenyl phosphate.[2] Bowers and McComb[3] improved the method of Bessey et al. to include a kinetic measurement. Tietz et al.[4] optimized this method to	Same

[1] King EJ, Armstrong AR. A convenient method for determining serum and bile phosphatase activity. *Can Med Assoc J* 1934;31:376–381.

[2] Bessey OA, Lowry OH, Brock MJ. A method for the rapid determination of alkaline phosphatase with five cubic millimeters of serum. *J Biol Chem* 1946;164:321–329.

[3] Bowers GN, McComb RB. A continuous spectrophotometric method for measuring the activity of serum alkaline phosphatase. *Clin Chem* 1966;12(2):70–89.

[4] Tietz NW, Burtis CA, Duncan P, et al. A reference method for measurement of alkaline phosphatase activity in human serum. *Clin Chem* 1983;29(5):751–761.

<table>
<tr><th>Characteristics</th><th>Subject Device:
Alkaline Phosphatase</th><th>Cleared Predicate Device:
Alkaline Phosphatase
Special 510(k) k023807</th></tr>
<tr><td></td><td>include a chelated metal-ion buffer of zinc, magnesium, and HEDTA. This Alkaline Phosphatase procedure is a modification of this method. Alkaline phosphatase in the sample catalyzes the hydrolysis of colorless p-nitrophenyl phosphate (p-NPP) to give p-nitrophenol and inorganic phosphate. At the pH of the assay (alkaline), the p-nitrophenol is in the yellow phenoxide form. The rate of absorbance increase at 404 nm is directly proportional to the alkaline phosphatase activity in the sample.
Optimized concentrations of zinc and magnesium ions are present to activate the alkaline phosphatase in the sample.</td><td></td></tr>
<tr><td>Use of Calibrators</td><td>No</td><td>Same</td></tr>
<tr><td>Use of Controls</td><td>Yes</td><td>Same</td></tr>
<tr><td colspan="3">General Device Characteristic Differences</td></tr>
<tr><td>Legal Manufacturer</td><td>Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany</td><td>Abbott Laboratories
Abbott Park, IL 60064, USA</td></tr>
<tr><td>R2 Reagent Formulation</td><td>
<table>
<tr><th>Ingredients</th><th>Concentration</th></tr>
<tr><td>4-nitrophenyl phosphate</td><td>> 171.6 mmol/L</td></tr>
<tr><td>Tris hydroxymethyl aminomethane</td><td>1.12%</td></tr>
<tr><td>Sodium Chloride</td><td>0.001%</td></tr>
<tr><td>4-Hydroxybenzoic acid</td><td>5.6%</td></tr>
<tr><td>Proclin 300</td><td>0.5 g/L</td></tr>
<tr><td>Proclin 950</td><td>1 g/L</td></tr>
</table>
</td><td>
<table>
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</table>
</td></tr>
<tr><td>Reagent Kit Components</td><td>Reagent Kit (List Number 7D55-32)
Reagent 1 (R1) 10 x 84 mL
Reagent 2 (R2) 10 x 26 mL
Estimated tests per kit: 11,358

Reagent Kit (List Number 7D55-22)</td><td>Reagent Kit (List Number 7D55-20)
Reagent 1 (R1) 10 x 84 mL
Reagent 2 (R2) 10 x 35 mL
Estimated tests per kit:11,358

Reagent Kit (List Number 7D55-30)</td></tr>
</table>

Characteristics	Subject Device: Alkaline Phosphatase	Cleared Predicate Device: Alkaline Phosphatase Special 510(k) k023807
	Reagent 1 (R1) 5 x 21 mL Reagent 2 (R2) 5 x 9 mL Estimated tests per kit: 1,500	Reagent 1 (R1) 5 x 48 mL Reagent 2 (R2) 5 x 22 mL Estimated tests per kit: 3,165
Assay Parameters, Assay Volume Requirements	R1 R2 Reagent volume: 60 20 Water volume: 125 45	R1 R2 Reagent volume: 60 20 Water volume: 170 0
Lower Limits of Measurement	Limit of Detection: 5.0 U/L Limit of Quantitation: 5.0 U/L	Limit of Detection: 1.9 U/L Limit of Quantitation: 5.0 U/L
On-Board Stability	8 Days	13 Days
Tube Types	Serum: - Serum tubes - Serum separator tubes Plasma: - Lithium heparin tubes - Lithium heparin separator tubes - Sodium heparin tubes	Serum: - Serum tubes - Serum separator tubes Plasma: - Lithium heparin tubes - Ammonium heparin - Sodium heparin tubes
Linearity	Linear up to 2,200 U/L (2343 U/L using IFCC factor) Flex Rate Linearity is 4555 U/L (4851 U/L using IFCC factor)	Linear up to 2200 U/L Flex Rate Linearity up to 4555 U/L
Standardization	Molar extinction of *p-nitrophenol* (non-IFCC method) IFCC* reference method	Molar extinction of *p-nitrophenol* (non-IFCC method)
Calibration Method	Factor Method (calibration factor of 2150, original, or 2290, traceable to IFCC)	Factor Method (calibration factor of 2150)

* IFCC = International Federation of Clinical Chemistry and Laboratory Medicine

VIII. Non-Clinical and/or Clinical Tests Summary & Conclusions

The Alkaline Phosphatase assay, evaluated using the optional calibration factor of 2290 on the ARCHITECT c System, met the pre-defined product requirements for all characteristics evaluated in the verification studies

The IFCC calibration factor (2290) represents only a mathematical factor change from the non-IFCC factor. Use of the IFCC calibration factor results in a 6.5% increase in reported results throughout the measurement range of the assay when compared to the unmodified predicate device. A shift of 6.5% is within the acceptable assay bias specifications (up to +/-10%) and thus does not have a potential to cause incorrect results. Furthermore, since the IFCC calibration factor is optional, it requires the customer to manually change the calibration factor parameter in the instrument, so the customer would be aware when they switched to using the IFCC calibration factor and would therefore be aware of the potential shift in results.

In addition to the implementation of the optional IFCC-based calibration factor, several other changes were made to the device since its clearance in 2002. Abbott performed a comprehensive risk-based assessment for each of the changes listed in the Alkaline Phosphatase Special 510(k) (K240468). The assessment includes all risks associated with each device modification, risk control measures to mitigate each identified risk, and the verification and/or validation activities required (including a summary of test methods, acceptance criteria, results, and why each is adequate to support substantial equivalence). The risk control measures show that the accumulated modifications did not impact the performance of the device. In conclusion, the modified device is therefore deemed to be substantially equivalent to the predicate device (cleared under K023807) as demonstrated by results obtained in the studies.