March 20, 2024

PHC Corporation
Helen Landicho, RAC
SVP Regulatory Affairs
Polymedco, Inc.
510 Furnace Dock Road
Cortlandt Manor, New York 10567

Re: K231974
Trade/Device Name: PATHFAST®hs-cTnI-II
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: March 1, 2024
Received: March 4, 2024

Dear Helen Landicho:

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.

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.
Acting Deputy Division 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K231974

Device Name
PATHFAST®hs-cTnI-II

Indications for Use *(Describe)*

PATHFAST® hs-cTnI-II is an in vitro diagnostic test for the quantitative measurement of cardiac Troponin I (cTnI) in heparinized or EDTA whole blood and plasma. Measurements of cardiac Troponin I are used as an aid in the diagnosis of acute myocardial infarction (AMI). PATHFAST® hs-cTnI-II is for use in clinical laboratory or point of care (POC) settings.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY K231974
PATHFAST® hs-cTnI-II
High Sensitive Troponin

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Federal Food, Drug, and Cosmetic Act and 21 CFR 807.92.

510(k) Owner:
PHC Corporation
1460-6 Aza-Mitodai, Mito, Tako-machi
Katori-gun, Chiba 289-2247, Japan
Misato Igarashi Ph.D.
81-3-6400-2115 (Tel)
81-3-5577-0451(Fax

Contact Person:
Polymedco, Inc.
Helen Landicho, RAC
914.293.1605 (Tel)

Name of the device

Trade name: PATHFAST® hs-cTnI-II
Common name: high sensitive Troponin I
Classification: 21 CFR 862.1215 Creatine Phosphokinase/creatine kinase or isoenzymes test system
Product code: MMI

Legally marketed device claiming equivalence:

PATHFAST® cTnI-II (k100130)

Device description:

The PATHFAST® hs-cTnI-II test is a chemiluminescent enzyme immunoassay performed on the PATHFAST® instrument.

Patient samples, whole blood or plasma, are dispensed by the operator into the designated area on the reagent cartridge. The instrument combines the patient sample, the antibody coated magnetic particles, and the alkaline phosphatase conjugate and incubates the mixture for 5 minutes at 37°C. During this incubation, the analyte in the patient sample binds to the antibody on the coated particles, and the alkaline phosphatase conjugate binds to the analyte-antibody coated-particle.

After the incubation, the instrument performs Bound/Free (B/F) separation using Magtration® technology to remove any excess unbound reagents. The chemiluminescent

substrate is then added. The substrate is catalyzed by the bound alkaline phosphatase, which results in emission of photons.

The photo-multiplier tube in the PATHFAST® instrument detects the photons that are emitted during the reaction. The chemiluminescent count is converted to analyte concentration values by the instrument based on the master calibration curve for the reagent lot.

The PATHFAST® hs-cTnI-II test is supplied in reagent kits. Each kit contains sufficient materials for 60 determinations. The calibrator materials are included with the reagent kit and are also available separately. Calibration kits and diluent kits are also provided separately.

Contents of the PATHFAST® hs-cTnI-II reagent kit

Component	Quantity
Reagent Cartridge	6 cartridges x 10 trays
Calibrator 1	2 vials
Calibrator 2	2 vials
Calibrator diluent	4 vials of 1.0 mL each

Reagent Cartridge: The reagent cartridge contains 16 wells. Wells 1, 6, 8, 9, 10, 12, 14, 15, 16 are empty. The other wells are filled with the following reagents:

Contents of the PATHFAST® hs-cTnI-II reagent cartridge

Reagent Description	Volume	Cartridge Well
Alkaline phosphatase (calf intestine) conjugated anti cTnI monoclonal antibody (mouse) in MES buffer (pH 6.0) with 0.007% zinc chloride, and 0.06% sodium azide as preservative	50 µl	2
Washing Buffer: Tris buffer (pH 7.5) with 0.05% sodium azide as preservative	400 µl	3, 4, 5
Magnetic particles coated with anti cTnI monoclonal antibody (mouse) in MOPS buffer	50 µl	7
Sample Dilution Buffer: Tris buffer (pH 8.2) with 0.05% sodium azide as preservative	25 µl	11
Chemiluminescent substrate: CDP-Star	100 µl	13

Calibrator 1: Lyophilized preparation containing MES pH 6.0, lactose, and enzyme free human serum, DTT

Calibrator 2: Lyophilized preparation containing cTnI complex, MES pH 6.0, lactose, and enzyme free human serum, DTT

Calibrator diluent: Aqueous solution with 0.05% sodium azide used for reconstituting Calibrators 1 and 2

Calibrator 1 and Calibrator 2 contain human serum obtained from donors who were confirmed negative for anti-HIV-1/2, HbsAg and Anti-HCV.

Intended use:

PATHFAST® hs-cTnl-Il is an in vitro diagnostic test for the quantitative measurement of cardiac Troponin I (cTnl) in heparinized or EDTA whole blood and plasma. Measurements of cardiac Troponin I are used as an aid in the diagnosis of acute myocardial infarction (AMI). PATHFAST® hs-cTnl-II is for use in clinical laboratory or point of care (POC) settings.

The indications for use are identical to the predicate assay. The PATHFAST® hs-cTnI-II modified the reporting units from ng/mL to the conventional ng/L and extended the reportable range from 4.1 ng/L to 50,000 ng/L. The modification of the units and reportable range of the device does not affect the diagnostic or clinical utility of the device or the safety and effectiveness of the device when used as labeled.

Comparison with the predicate device

Similarities		
Item	Candidate Device PATHFAST hs-cTnI-II	Predicate Device PATHFAST cTnI-II K100130
Intended Use	Assist in the diagnosis of acute myocardial infarction. For use in clinical laboratory or point of care (POC) settings.	Same
Storage	2-8º C	2-8º C
Calibration Levels	6	6
Methodology	Chemiluminescent enzyme immunoassay	Same
Indications for use	Assist in the diagnosis of acute myocardial infarction. For use in clinical laboratory or point of care (POC) settings. Not for risk stratification	Same
Sample Types	EDTA and Lithium heparin whole blood and plasma	Same

Differences		
Item	Candidate Device PATHFAST hs-cTnI-II	Predicate Device PATHFAST cTnI-II K100130
Reportable range	4.1 to 50,000 ng/L	0.019 to 50 ng/mL

Modification of the reporting units from ng/mL to ng/L meets conventional laboratory reporting for troponin.

Non clinical testing:

Precision, reproducibility, point of care precision reproducibility studies, high dose hook, traceability, stability, expected values, analytical specificity, assay cut-off, comparison studies, matrix studies, clinical sensitivity, clinical specificity, clinical cut-off and reference ranges are reported in K100130 PATHFAST® cTnI-II IFU.

Linearity/assay reportable range:
Linearity studies were conducted on EDTA and lithium heparin whole blood and plasma samples. For the PATHFAST® hs-cTnI-II, the measurement procedure shows linearity for the interval from 4.1 to 50,000 ng/L, with deviations from linearity within ±10%.

EDTA whole blood and plasma samples, and lithium heparin whole blood and plasma samples with low and high values were diluted to produce up to 12 dilution levels per each unique series with values ranging from 1 to 64,500 ng/L. Three-dilution series of each sample matrix were tested across three different lots of reagents. Each level was tested in replicates of three. The acceptable coefficient of variation for the replicates was set at <20%. The relative concentration, measured values, predicted values, deviations from linearity and percent deviations were analyzed for each sample in a series. The %CV for the replicates was set at <20% and the allowable deviation from linearity was acceptable within ±10%. The maximum absolute deviation observed in the linearity study across all sample matrices was 9.7%

Detection limit:
LoB/LoD studies were conducted using EDTA and lithium heparin whole blood and plasma samples. The LoB was determined by testing four lots of reagents, four plasma samples, replicates of two per sample, repeated twice a day for three consecutive business days. Each lot had a total of 24 replicates for a combined number of 96 determinations. The LoD for EDTA and lithium heparin whole blood and plasma was determined by testing 4 low samples, twice a day with four lots of reagent over three days for a total of 96 replicates.

The LoQ study was conducted using EDTA and lithium heparin whole blood and plasma samples at the estimated concentration where the coefficient of variation for the replicates was < 20%. Two sets of three samples and two reagent lots; each tested in replicates of four, three runs per day, for a total of 24 replicates per sample. Testing was repeated for each matrix. The coefficient of variations and means were calculated and pooled for each sample per reagent lot. The LoQ for EDTA and lithium heparin whole blood and plasma was determined by averaging the values over two lots. Lowest hs-cTnI concentration of the samples that showed less than 20 % CV.

Summary:

	EDTA		LiHep	
	WB	Plasma	WB	Plasma
LoB	1.466	1.466	1.466	1.466
LoD	2.991	2.958	2.942	3.002
LoQ	4.1	4.1	4.1	4.1

$LoD = LoB + c_{\rho}SD_L$ where $c_{\rho} = 1.645/1-(1/4*(L - J))$
[c] LoQ = minimum cTnI concentration with % CV < 20 %
The measuring range of the cTnI-II assay is from 4.1 ng/L to 50,000 ng/L.

The analytical information in this premarket notification supports the measuring range of the PATHFAST® hs-cTnI of 4.1 ng/L to 50,000 ng/L

Clinical performance:

The effects of the modification of the LoQ were evaluated on the previously reported clinical claims from the predicate device. During the predicate reference range study used to establish the 99th percentile cutoff all values below 0.019 ng/mL were reported as numerical results. The data set used to non-parametrically calculate the 99th percentile consisted entirely of numerical results. The predicate LoQ was the lowest concentration at which there was an imprecision of 10% CV; the updated LoQ is the lowest concentration at which there was an imprecision of 20% CV, which is 4.1 ng/L.

There is no impact on the 99th percentile cutoff of the reference range validated in K100130 with the updated LoQ of 4.1 ng/L, because the original numerical results for all testing were previously used in the calculation. The PATHFAST® hs-cTnI-II assay continues to meet the criteria that measurable concentrations are above the limit of detection for over 50% of healthy individuals. The 99th percentile cutoff remains at 29 ng/L.

The clinical sensitivity and specificity of the PATHFAST® hs-cTnI-II assay is not affected by lowering the LoQ to 4.1 ng/L, as all the numerical data was included in the predicate calculations. The clinical sensitivity and specificity remain unchanged when lowering the LoQ to 4.1 ng/L.

The evidence supports that the non-parametrically calculated cutoff at the 99th percentile remains at 29 ng/L and the assay continues to meet the criteria that measurable concentrations are above the limit of detection for over 50% of healthy individuals. The clinical sensitivity and specificity of the assay remain unchanged from the predicate device.

Summary conclusion:

The summary includes conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is safe, effective and performs as wells as or better than the predicate device. The information provided in this submission is complete and demonstrates that the subject device is substantially equivalent to the predicate device.