1.0 Submitted By

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2.0 Device Name:

2.1 **Trade Name:** PK7400 Automated Microplate System
2.2 **Common Name:** PK7400
2.3 **Classification Name:** System, Test, Automated Blood Grouping and Antibody
2.4 **Product Code:** KSZ
2.5 **Device Class:** II
2.6 **Regulation Number:** 21 CFR 864.9175

3.0 Predicate Device

Legally Marketed Device	Manufacturer	510(k) Number	Clearance Date
PK7300 Automated Microplate System	Beckman Coulter, Inc.	BK060024	May 14, 2007

4.0 Device Description

The Beckman Coulter PK7400 Automated Microplate System is a high throughput, fully automated, batch test system that consists of an analyzer, console and printer. The operation, and testing of donor blood samples using designated reagents, is fully controlled by the PK7400 software. System controls include process controls such as reagent volume monitoring, clot detection, and a 30°C incubation area that is monitored throughout testing, by the analyzer software. The PK7400 analyzer is the fourth generation of the PK7000 series of analyzers. It utilizes the same testing methodologies as its predecessors and is a closed system that will utilize reagents specifically developed for the PK System Analyzers. The maximum processing speed is 300 samples per hour.

5.0 Intended Use

The Beckman Coulter PK7400 Automated Microplate System is a high throughput, fully automated, batch test system that uses agglutination technology with Beckman Coulter terraced microplates. The PK7400 performs donor ABO blood grouping, Rh typing, including weak D testing, and red blood cell antigen screening using Diagast reagents. The PK7400 is also intended for use with specific qualitative infectious disease assays

that are cleared or approved and are labeled indicating their use on this system for blood donor screening. This system is for in vitro diagnostic use only.

6.0 Comparison to the Predicate

The PK7400 is the successor to the PK7300 Automated Microplate System. These devices have same / similar design and modes of operation. An overview of the functional similarities and differences are summarized in Table 6.0**.**

Table 6.0 - Predicate Device Comparison Overview

Feature	Predicate Device: PK7300 (BK060024)	Candidate Device: PK7400
Intended Use:	The Beckman Coulter PK7300 Automated Microplate System is a completely automated analyzer intended exclusively for agglutination technology using Beckman Coulter terraced microplates. The PK7300 can be used to perform donor ABO/Rh blood grouping, including weak D testing, Rh-Kell phenotyping, syphilis (TP), and CMV qualitative screening.	The Beckman Coulter PK7400 Automated Microplate System is a high throughput, fully automated, batch test system that uses agglutination technology with Beckman Coulter terraced microplates. The PK7400 performs donor ABO blood grouping, Rh typing, including weak D testing, and red blood cell antigen screening using Diagast reagents. The PK7400 is also intended for use with specific qualitative infectious disease assays that are cleared or approved and are labeled indicating their use on this system for blood donor screening. This system is for in vitro diagnostic use only.
Methodology:	Passive hemagglutination using Beckman Coulter terraced microplates	Same as predicate
Operating System	Support Windows Embedded Standard 2009	Microsoft Windows - 10 IOT
System Software & Firmware	The operation of the analyzer and data processing tasks are controlled by PK7300 software (not the OS). In addition, the analyzer is controlled by firmware and the data processing tasks by the PK7300 software and application programming interface (API).	The operation of the analyzer and data processing tasks are controlled by PK7400 software (not the OS). In addition, the analyzer is controlled by firmware and the data processing tasks by the PK7400 software and application programming interface (API). The software restricts use of reagents only to those authorized by Beckman Coulter.
Other	Not Applicable	Fully RoHS compliant
Throughput	300 samples per hour	Same as predicate

Feature	Predicate Device: PK7300 (BK060024)	Candidate Device: PK7400
Sample	Whole Blood, Serum, Plasma, or red blood cell suspension	Whole Blood, Serum, Plasma
Sample Detection	• Detection of red blood cells and plasma via probe electrodes. • Clog detection for plasma probe	• Detection of red blood cells and plasma via probe electrodes. • Clog detection for plasma and red blood cell, plasma probes.
Incubation Settings	Temperature: 30 C Time: 60 minutes	Temperature: 28 C Time: 60 minutes
Reaction Monitoring	Temperature and humidity of the reaction incubator monitored and alarmed.	Same as predicate
User Traceability	Barcoded Samples Barcoded Reagents & Diluents Barcoded Microplates	Same as predicate
Photometry System	Scanning photometer system of each plate well with a high precision Charged Coupled Device (CCD) color camera (analog).	Scanning photometer system of each plate well with a high precision Charged Coupled Device (CCD) color camera (digital).
Reaction & Test Interpretation	• Image analysis & reaction interpretation are based on measurements taken inside and outside the well. Decision logic utilizes these measurements with defined thresholds to interpret each reaction in each microplate well. Those parameters are: • Values for each of these three measurements are assessed against pre-programmed thresholds to interpret the reaction in each well as “+”, “-“, or “?”. The reaction interpretations for each well are then compared to test logic tables to obtain the interpretation (result) for each test. • Additionally, the image is provided on the PC for visual review.	Same as predicate
Image Archive	Images can also be archived to storage media (CD-ROM, DVD, Floppy Disk, or uploaded to an external software archive device.	Images can also be archived to storage media (USB device) or uploaded to an external software archive device.

8.0 Performance Testing

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to the PK7300 Automated Microplate System already in commercial distribution. Equivalence is demonstrated through method comparison, reproducibility and repeatability and other studies.

8.1 Clinical Studies

Results from the PK7400 and reagents intended for use with the PK7400 for blood donor testing were compared to results from the PK7300 and associated on-market reagents for blood donor testing in three geographically diverse clinical study sites. In addition, testing was conducted by each of the study sites, using the same panel of samples, to demonstrate reproducibility and/or repeatability under the testing conditions described by the Instructions for Use for each reagent.

8.2 Non-Clinical Studies

Non-clinical studies were conducted in-house by the reagent manufacturers to verify performance of the reagents on the PK7400. Data from these studies was used to demonstrate the ability of the PK7400 together with the reagents to detect weakly reactive samples or those with weak or variant antigen expressions.

Conclusion:

The PK7400 Automated Microplate System is substantially equivalent to the PK7300 Automated Microplate System. The devices have same / similar design and modes of operation. The similarities and differences are summarized in table (Table 6.0). Substantial equivalence has been demonstrated through performance of donor ABO/Rh, Rh and Kell phenotyping with Diagast reagents. Performance testing conducted verifies that the device functions as intended and that design specifications have been satisfied.

This 510(k) summary is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.