DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Beckman Coulter, Inc.
Geraldine Fuentespina
Manager, Regulatory Affairs
250 S. Kraemer Blvd., Mail Stop E1.SE.01
Brea, CA 92821

January 9, 2017

Re: [510(k) Number] K162208
Trade/Device Name: IgG
Regulation Number: 21 CFR 866.5510
Regulation Name: Immunoglobulins A, G, M, D, and E immunological test system
Regulatory Class: Class II
Product Code: CFN, JJE
Dated: November 29, 2016
Received: November 30, 2016

Dear Ms. Fuentespina:

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 (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. 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.

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 Parts 801 and 809**]**); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

FDA Kelly Oliner -S

FOR,
Leonthena R. Carrington, MS, MBA, MT (ASCP)
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162208

Device Name
IgG

Indications for Use *(Describe)*

System reagent for the quantitative determination of IgG immunoglobulins in human serum, plasma and cerebrospinal fluid on Beckman Coulter AU analyzers. The measurement of IgG aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

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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1.0 Submitted By

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2.0 Date of Preparation

6 January 2017

3.0 Device Name(s)

Proprietary Name: IgG
Common Name: IgG
Classification: Class II
Classification Name: Immunoglobulins A, G, M, D, E Immunological Test System
Product Codes: CFN
Regulation Number: 21 CFR 866.5510

4.0 Predicate Device

Candidate(s)	Predicate	Manufacturer
IgG	Olympus IgG Reagent (K073490)	Beckman Coulter, Inc.

5.0 Device Description

The device consists of two reagents: R1 buffer (Tris buffer pH 7.2, polyethylene glycol 6000) and R2 (goat anti-IgG antiserum). The reagents contain sodium azide as preservative.

When a sample is mixed with R1 buffer and R2 antiserum solution, human IgG reacts specifically with anti-human IgG antibodies to yield insoluble aggregates. Immune complexes formed in solution scatter light in proportion to their size, shape and concentration. Turbidimeters then measure the reduction of incidence light due to reflection, absorption or scatter. In the AU procedure, the decrease in intensity of light transmitted (increase in absorbance) through particles suspended in solution is as a result of complexes formed during the antigen-antibody reaction.

6.0 Indications for Use

System reagent for the quantitative determination of IgG immunoglobulins in human serum, plasma and cerebrospinal fluid on Beckman Coulter AU analyzers. The measurement of IgG aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

For in vitro diagnostic use.

7.0 Comparison to the Predicate

The formulation of the candidate IgG reagent and the predicate IgG reagent are identical. The following tables show the similarities and differences between the predicate device.

Table 7.0 - IgG Predicate Device Comparison Table

Feature		Predicate Device: IgG Reagent (K073490)	Candidate Device: IgG Reagent
Item Number		IgG (OSR6X172) reagent	Same
Intended Use		System reagent for the quantitative determination of IgG immunoglobulins in human serum, plasma and cerebrospinal fluid on Beckman Coulter AU analyzers	Same
Measurement		Quantitative	Same
Instrument Required		AU400/400^{e}/480, AU600/640/640^{e}/680 and AU2700/5400/AU5800 Beckman Coulter Analyzers	AU400/400^{e}/480, /640/640^{e}/680, AU2700/5400/AU5800 and DxC 700 AU Beckman Coulter Analyzers.
Methodology		Immunoturbidimetric	Same
Antibody		Goat anti-IgG	Same
Reagent form and storage		Liquid, on-board storage	Same
Specimen Type		Serum, EDTA or Lithium heparin plasma, and cerebrospinal fluid	Same
Calibrator		Serum Protein Multi-Calibrator (Cat # ODR3021)	Same
Onboard Stability		90 Days	Same
Calibration Stability	Serum & Plasma	90 Days	Same
	CSF	2 Days	Same
Analytic Range	Serum & Plasma	75 – 3000 mg/dL	Same
	CSF	2 – 50 mg/dL	Same

Feature		Predicate Device: IgG Reagent (K073490)	Candidate Device: IgG Reagent
Precision	Serum & Plasma	With-run: ≤ ±3.5% mg/dL Total: < ±6.0% mg/dL	Same
	CSF	With-run: ≤ ±6.0% or ±0.4 mg/dL Total: < ±7.5% or ±0.5mg/dL	Same
Sensitivity	Serum & Plasma	LoQ: 75 mg/dL	Same
	CSF	LoQ: 2 mg/dL	Same
Interference	Serum & Plasma	Bilirubin: Interference less than 3% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 3% up to 500 mg/dL Hemolysate Lipemia: Interference less than 5% up to 1000 mg/dL Intralipid RF: Interference less than 7% up to 1200 IU/mL Rheumatoid Factor	Similar The criteria for No Significant Interference (NSI) is recovery within 10% of the initial value. Bilirubin: NSI up to 40 mg/dL Bilirubin Hemolysis: NSI up to 500 mg/dL Hemolysate Lipemia: NSI up to 1000 mg/dL Intralipid RF: NSI up to 1200 IU/mL Rheumatoid Factor

Feature		Predicate Device: IgG Reagent (K073490)	Candidate Device: IgG Reagent
	CSF	Bilirubin: Interference less than 3% up to 40 mg/dL Bilirubin Hemolysis: Interference less than 3% up to 500 mg/dL Hemolysate Lipemia: Interference less than 5% up to 1000 mg/dL Intralipid RF: Interference less than 7% up to 1200 IU/mL Rheumatoid Factor	Similar The criteria for No Significant Interference (NSI) is recovery within 10% of the initial value. Bilirubin: NSI up to 40 mg/dL Bilirubin Hemolysis: NSI up to 500 mg/dL Hemolysate Lipemia: NSI up to 1000 mg/dL Intralipid RF: NSI up to 1200 IU/mL Rheumatoid Factor

8.0 Comparison testing

IgG assay was selected as the representative immunoturbidimetry assay for the DxC 700 AU Clinical Chemistry Analyzer. In order to demonstrate the comparability between the predicate device, AU5800 and the candidate device, DxC 700 AU, the following performance testing was conducted on the IgG Assay:

Method Comparison
Linearity
Sensitivity
Reference Interval
Interference
In use (On board) & Calibrator Stability
Precision
Prozone
Auto-dilution

All other immunoturbidimetric reagent applications will be validated using risk management, design controls, and FDA's Guidance for Industry and FDA staff - Replacement Reagent and Instrument Family Policy. The core validation principles are linearity, method comparison, precision, sensitivity, interference, reference interval, prozone tolerance and on-board/calibration frequency studies. Reference ranges will be verified.

9.0 Summary of Performance Data

The data contained in the Premarket Notification supports the substantial equivalence of the IgG reagent to the predicate IgG reagent already in commercial distribution. Equivalence is demonstrated through method comparison, linearity, imprecision and sensitivity experiments.

10.0 Conclusion

The IgG Reagent on the DxC 700 AU Clinical Chemistry Analyzer is identical in design and composition as the IgG Reagent on AU Systems cleared under K073490. Method comparison, linearity, sensitivity, reference interval, interference, precision, prozone, stability testing demonstrates that the assay performance is substantially equivalent between the candidate system and the predicate.

Substantial equivalence of the immunoturbidimetric assays has been demonstrated through performance of IgG. 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.