DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 8, 2016

Beckman Coulter Ireland, Inc.
Ms. Eimear Carr
Regulatory Affairs Specialist
Lismeehan, O'Callaghan's Mills,
Co. Clare, Ireland

Re: K161297
Trade/Device Name: βeta-2-Microglobulin
Regulation Number: 21 CFR 866.5630
Regulation Name: Beta-2-microglobulin immunological test system
Regulatory Class: II
Product Code: JZG
Dated: May 5, 2016
Received: May 9, 2016

Dear Ms. Carr:

This letter corrects our substantially equivalent letter of June 7, 2016.

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 and 809), 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 yours,

Kelly Oliner -S

For
Leonthena 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

Enclosure

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)*

Device Name
βeta-2-Microglobulin

Indications for Use *(Describe)*
System reagent for the quantitative determination of β-2-Microglobulin (β2M) in human serum on Beckman Coulter AU analyzers

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.

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510k Summary
βeta-2-Microglobulin

1.0

Submitted By:
Eimear Carr
Regulatory Affairs Specialist
Beckman Coulter Ireland, Inc.
Lismeehan, O'Callaghan's Mills
Co. Clare, Ireland
Telephone: +353-65-683-1483
Fax: +353-65-683-1122
Email: ecarr@beckman.com

2.0 Date of Preparation:

05th May, 2016

3.0 Device Identifications

Proprietary Name:	βeta-2-Microglobulin
Common Name:	βeta-2-Microglobulin
Classification:	Class II
Product Codes:	JZG
Regulation Number:	21 CFR 866.5630

4.0 Predicate Device:

Proposed Device	Predicate	Manufacturer	Docket Number
βeta-2-Microgloublin	β-2-Microgloublin	K991136	Olympus America Inc./ Beckman Coulter Inc.

The βeta-2-Microglobulin reagent is substantially equivalent to the Beckman Coulter product listed above currently in commercial distribution.

5.0 Description:

The βeta-2-Microglobulin reagent kit is a System Reagent for the Quantitative determination of β-2-Microglobulin (β-2-M) in human serum on Beckman Coulter AU analyzers.

The βeta-2-Microglobulin kit is a liquid, ready to use and consists of 4 x 10mL R1 reagent vials and 4 x 8mL R2 reagent vials. Immune complexes formed in solution scatter light in proportion to their size, shape and concentration. Turbidimeters measure the reduction of incident light due to reflection, absorption, or scatter.

In the procedure, the measurement of the decrease in light transmitted (increase in absorbance) through particles suspended in solution as a result of complexes formed during the antigen-antibody reaction, is the basis of this assay.

The βeta-2-Microglobulin reagent is designed for optimal performance on Beckman Coulter AU analyzers.

6.0 Intended Use:

System reagent for the quantitative determination of β-2-Microglobulin (β-2-M) in human serum on Beckman Coulter AU analyzers. For In Vitro Diagnostic use only.

Clinical Significance:

β-2-Microglobulin occurs in serum, urine, cerebrospinal and other body fluids in low concentrations. Increased concentrations of β2M in serum are found in patients with renal diseases (due to reduced glomerular filtration) and active rheumatoid arthritis.

7.0 Comparison to Predicate(s):

The following tables shows similarities and differences between the predicate identified in Section 4.0 of this summary.

Test System	Predicate	Proposed Device
Proprietary and Established Names	β 2-microglobulin (K991136)	βeta-2-Microglobulin
Similarities		
Intended use	System reagent for the **quantitative determination of** β-2-Microglobulin (β2M) in **human serum** on OLYMPUS **analyzers.** .	**Similar** **System reagent for the quantitative determination of β-2-Microglobulin (β2M) in human serum** on Beckman Coulter AU **analyzers.**
Instrument Platforms	Olympus AU400, AU600, AU640 or AU1000 Chemistry analyzers	**Similar** Beckman Coulter analyzers AU400/400^{e}/480,

		AU600/640/640^{e}/680 and AU2700/5400/AU5800
Quality Control	At least two levels of appropriate β-2-Microglobulin control material such as Bio-Rad Liquichek should be tested a minimum of once a day.	**Similar** At least two levels of an appropriate quality control material should be tested a minimum of once a day.
Specificity (Interferences)	AU400: Ascorbate: <3% up to 20mg/dL Ascorbate Bilirubin: <3% up to 40 mg/dL Bilirubin Hemolysis:< 3% up to 500 mg/dL Hemolysate Lipemia: <10% up to 500 mg/dL Intralipid AU600/AU640: Ascorbate: <3% up to 20mg/dL Ascorbate Bilirubin: <3% up to 40 mg/dL Bilirubin Hemolysis:< 3% up to 500 mg/dL Hemolysate Lipemia: <3% up to 1000 mg/dL Intralipid AU1000: Ascorbate: <3% up to 20mg/dL Ascorbate Bilirubin: <3% up to 40 mg/dL Bilirubin Hemolysis:<4% up to 500 mg/dL Hemolysate Lipemia: <4% up to 1000 mg/dL Intralipid	**Similar** Within ± 10 % NSI for the following(NSI = No Significant Interference) Ascorbate 20 mg/dL Bilirubin 40 mg/dL Hemolysis 500 mg/dL Lipemia 500 mg/dL
Specimen Storage and Stability	Serum is the recommended specimen. Allow the sample to clot for 15-30 minutes at room temperature, then for 30 – 60 minutes at 4^{0}C. Centrifuge, separate the serum from the clot and store the serum in plastic tubes. Serum should be	**Similar** Literature reference A fasting serum specimen, free from hemolysis, is the recommended specimen. Avoid highly lipemic samples, which may produce

	stored in multiple aliquots to avoid thawing and refreezing.	excessively high scatter signals.
Measurement	Quantitative	Same
Reagent	Liquid, ready to use	Same
Technology	Immunological test system	Same
Operating Principle	Turbidimetric Method	Same
Reagent Formulation	Phosphate buffer, Latex particles coated with rabbit IgG anti-β-2-Microglobulin antibodies, Polyethylene Glycol, also contains preservatives	Same
Sample Types	Serum	Same
Reagent Storage / Closed Shelf life	2-8^{0}C until expiration date	Same
Calibrator	Serum Protein Multi-calibrator 2 (ODR3023)	Same
Reference Interval	0.097 – 0.184 mg/dL	Same
Reagent Material: Antibodies	Rabbit IgG anti-β-2-Microglobulin antibodies	Same
Reagent Material: Buffer	Phosphate buffer	Same
Dynamic Range / Linearity	0.05 – 1.6 mg/dL	Same

Precision Within Run	≤ 5% CV	Same
Precision Total	≤ 10% CV	Same

Differences between the Predicate Device and the Proposed Device:

Test System	**Predicate**	**Proposed Device**
Feature	β 2-microglobulin (K991136)	βeta-2-Microglobulin
Differences		
Reagent On-Board Stability	60 days	90 days
Calibration Frequency	14 days	90 days

8.0 Performance Characteristics - Analytical Performance

a. Stability: On-Board and Calibration Frequency

On-Board (OB) stability and calibration frequency testing was assessed in accordance with internal procedures. The aim was to establish a 90 day reagent on-board claim and a 90 day calibration frequency claim.
Testing was performed using one reagent lot. Calibration was performed on the first day. Controls were run to check calibration and the reagent. Linearity was run on the last number of shots of reagent. The maximum time point exceeded the claim. Calibration was performed again at day 90.
A 90 day reagent on-board claim, a 90-day calibration frequency claim was established.

9.0 Conclusion:

The conclusions drawn from the nonclinical tests (discussed above) demonstrate that the βeta-2-Microglobulin system reagent is as safe, as effective and performs as well as the predicate device. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.