DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 15, 2014

BECKMAN COULTER IRELAND, INC.
ANNE-MARIE SHINE
REGULATORY AFFAIRS SPECIALIST
LISMEEHAN, O'CALLAGHANS MILLS
CO. CLARE, IRELAND

Re: K142346
Trade/Device Name: Urine/CSF Albumin and Urine/CSF Albumin Calibrator
Regulation Number: 21 CFR 866.5040
Regulation Name: Albumin immunological test system
Regulatory Class: II
Product Code: DCF, JIT
Dated: August 20, 2014
Received: August 22, 2014

Dear Ms. Anne-Marie Shine:

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 regulations (21 CFR Parts 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" (21 CFR 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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology 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)*
K142346

Device Name
Urine/CSF Albumin and Urine/CSF Albumin Calibrator

Indications for Use *(Describe)*

Urine/CSF Albumin:
The Urine/CSF Albumin reagent is intended to be used for the quantitation of albumin concentration in human urine and cerebrospinal fluid (CSF) on the Beckman Coulter AU clinical chemistry systems as an aid in the diagnosis of kidney diseases. For in vitro diagnostic use only.

Urine/CSF Albumin Calibrator:
The Urine/CSF Albumin calibrator is intended to be used to calibrate the Urine/CSF Albumin reagent on the Beckman Coulter AU clinical chemistry systems. For in vitro diagnostic use only.

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.

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510(k) Summary k142346

Urine/CSF Albumin and Urine/CSF Albumin Calibrator

1.0 Submitted By:

Anne-Marie Shine
Regulatory Affairs Specialist
Beckman Coulter Ireland Inc.,
Lismeehan,
O'Callaghan's Mills,
Co. Clare,
Ireland.
Phone: +353-65-683-1138
FAX: +353-65-683-1122
email: amshine@beckman.com

2.0 Date Prepared:

20th August 2014

3.0 Device Identifications

Proprietary Name:	Urine/CSF Albumin and Urine/CSF Albumin Calibrator
Common Name:	Urine/CSF Albumin and Urine/CSF Albumin Calibrator
Classification:	Class II (Limitations tripped)/Class II
Product Codes:	DCF and JIS
Regulation Number:	21CFR 866.5040/862.1150

4.0 Predicate Devices

Urine Predicate

Proposed Device	Predicate Device	Manufacturer	Docket Number
Urine/CSF Albumin, Model Nos. B38858 B46435	SYNCHRON® Systems Microalbumin (MA) Reagent, Model No. 475100	Beckman Coulter, Inc.	K082251

CSF Predicate

Proposed Device	Predicate Device	Manufacturer	Docket Number
Urine/CSF Albumin, Model Nos. B38858 B46435	IMMAGE® Immunochemistry System Albumin (ALB) Reagent, Model No. 447600	Beckman Coulter, Inc. (Previously Beckman Instruments, Inc.)	K964695

Calibrator Predicate

Proposed Device	Predicate Device	Manufacturer	Docket Number
Urine/CSF Albumin Calibrator, Model No. B38859	SYNCHRON® Systems Microalbumin (MA) Calibrator, Model No. 475089	Beckman Coulter, Inc.	K000331

Urine/CSF Albumin and Urine/CSF Albumin Calibrator are substantially equivalent to the Beckman Coulter, Inc. predicate products listed above currently in commercial distribution.

5.0 Description

The Urine/CSF Albumin reagent kit is in a liquid, ready to use format. There are two kit concepts available. Each kit concept contains an R1 and an R2 reagent vial with different fill volumes. The Urine/CSF Albumin calibrator kit is in a liquid, ready to use format and contains 5 x 2 mL calibrator levels. It is packaged and sold separately to the reagent kit. Urine/CSF Albumin reagent is used to measure albumin concentration by a turbidimetric method. In the reaction, anti-human serum albumin antibodies combine with albumin from the sample to form immune complexes that scatter light in proportion to their size, shape and concentration. The absorbance of these aggregates is proportional to the albumin concentration in the sample. Change in absorbance is measured at 380nm with subtraction of a reference wavelength at 800nm. The Urine/CSF Albumin reagent and calibrator is designed for optimal performance on Beckman Coulter AU clinical chemistry analyzers.

The calibrator is manufactured from human material; therefore it should be handled as though capable of transmitting infectious disease. Each serum or plasma donor unit used in the preparation of this material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for the antibodies to HIV and HCV and nonreactive for HB_sAg. Because no test method can offer complete assurance that HIV, hepatitis B virus, and hepatitis C virus or other infectious agents are absent, this material and all patient samples should be handled as though capable of transmitting infectious disease. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled as specified in the Centers for Disease Control's Biosafety Level 2 guidelines.

6.0 Intended Use

Urine/CSF Albumin

The Urine/CSF Albumin reagent is intended to be used for the quantitation of albumin concentration in human urine and cerebrospinal fluid (CSF) on the Beckman Coulter AU clinical chemistry systems as an aid in the diagnosis of kidney diseases. *For in vitro* diagnostic use only.

Urine/CSF Albumin Calibrator

The Urine/CSF Albumin calibrator is intended to be used to calibrate the Urine/CSF Albumin reagent on the Beckman Coulter AU clinical chemistry systems. For in vitro diagnostic use only.

7.0 Comparison to the Predicate(s)

Urine/CSF Albumin claims to be substantially equivalent to the predicate identified in section 4. The following tables show similarities and differences between the reagent predicates and proposed device.

Urine Application

Test System	Urine Predicate	Proposed New System
Proprietary and Established Names	SYNCHRON® Systems Microalbumin (MA) Reagent	Urine/CSF Albumin
SIMILARITIES		
Intended use	MA reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems MA Calibrator is **intended for quantitative determination of Albumin concentration in human urine.**	Same The Urine/CSF Albumin reagent is **intended to be used for the quantitation of albumin concentration in human urine.**
Technology	Photometric	Same
Operating Principle	Turbidimetric Method	Same
Sample Types	Urine	Same
Reagent Material: Antibodies	Antibody specific for human albumin (goat polyclonal)	Same
Reagent Material: Buffer	Phosphate buffer with PEG	Same
Reagent On-Board Stability	60 days	Same
Reagent Storage/ Closed Shelf Life	2-8°C until expiration date	Same
Precision Within Run	≤ 5.4% CV or 0.125 mg/dL	Similar ≤ 5% CV or 0.1 mg/dL
Reference Interval	Reference Interval Based on Literature Reference: American Diabetes Association, "Diabetic Nephropathy", Diabetes Care, 20 [Suppl 1]: 524 7 (1997)	Same

Test System	Urine Predicate	Proposed New System
Proprietary and Established Names	SYNCHRON® Systems Microalbumin (MA) Reagent	Urine/CSF Albumin
DIFFERENCES		
Technology Type	Instrumentation: SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems	Instrumentation: Beckman Coulter AU clinical chemistry systems
Analyzers	SYNCHRON LX® Systems, UniCel® DxC 600/800 Systems	AU Clinical Chemistry Analyzers

CSF Application

Test System	CSF Predicate	Proposed New System
Proprietary and Established Names	IMMAGE® Immunochemistry System Albumin (ALB) Reagent	Urine/CSF Albumin
SIMILARITIES		
Intended use	ALB reagent, when used in conjunction with IMMAGE® Immunochemistry Systems and Calibrator 3, **is intended for quantitative determination of Albumin (ALB)** in human serum or **cerebrospinal fluid (CSF)** by rate nephelometry.	Same The Urine/CSF Albumin reagent is **intended to be used for the quantitation of albumin concentration in cerebrospinal fluid (CSF).**
Technology	Photometric	Same
Reagent Material: Antibodies	Antibody specific for human albumin (goat polyclonal)	Same
Reagent Material: Buffer	Phosphate buffer with PEG	Same
Sample Types	Serum and **CSF**	Similar CSF
Reagent Storage/ Closed Shelf Life	2-8°C until expiration date	Same

Test System	CSF Predicate	Proposed New System
Proprietary and Established Names	IMMAGE® Immunochemistry System Albumin (ALB) Reagent	Urine/CSF Albumin
DIFFERENCES		
Technology Type	Instrumentation: Beckman IMMAGE Immunochemistry Systems	Instrumentation: Beckman Coulter AU clinical chemistry systems
Operating Principle	Rate nephelometry	Turbidimetric
Analyzers	IMMAGE Immunochemistry System	AU Clinical Chemistry Analyzers
Sample Types	**Serum** and CSF	CSF

Urine/CSF Albumin Calibrator claims to be substantially equivalent to the predicate identified in section 4. The following table shows similarities and differences between the calibrator predicate and proposed device.

Test System	Calibrator Predicate	Proposed New System
Proprietary and Established Names	SYNCHRON® Systems MA Calibrator	Urine/CSF Albumin Calibrator
SIMILARITIES		
Intended use	MA Calibrator, when used in conjunction with SYNCHRON Systems MA Reagent (P/N 475100), is intended for use on the SYNCHRON LX® and UniCel® DxC Systems **for the calibration of Microalbumin**.	Similar The Urine/CSF Albumin calibrator is intended to be used **to calibrate the Urine/CSF Albumin reagent** on the Beckman Coulter AU clinical chemistry systems. For *in vitro* diagnostic use only.
Single Constituent Calibrator Composition	pH buffered human serum albumin	Same
Calibrator Matrix Base	Aqueous pH buffer	Same
Calibrator Traceability	ERM®- DA470	Same
Calibrator Storage/ Closed Shelf Life	2-8°C until expiration date	Same

Test System	Calibrator Predicate	Proposed New System
Proprietary and Established Names	SYNCHRON® Systems MA Calibrator	Urine/CSF Albumin Calibrator
DIFFERENCES		
Calibrator	SYNCHRON® Systems MA Calibrator 475089 (1 Level)	Urine/CSF Albumin Calibrator B38859 (5 levels)
Calibration Frequency	Every 30 days	Every 60 days

8.0 Performance Characteristics - Analytical Performance

a. Precision

Within run (repeatability) and total imprecision (within laboratory) studies were designed from CLSI guideline EP05-A2 *"Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition".* All testing was carried out using an AU5800 analyzer.

Pooled human urine samples were spiked using purified human serum albumin and used for the urine pools. Pooled human CSF samples were either diluted using 0.9% saline or spiked using purified human serum albumin and used for the CSF pools.

The experimental design utilized duplicate sample analysis, twice daily, over the course of 20 working days (n=80) for 3 sample levels. There was a minimum interval of 2 hours between the two runs on each day. The results are presented in the table below:

Sample Type	Pool	Mean mg/dL	Repeatability/ Within-Run		Within Laboratory/ Total	
			SD mg/dL	CV %	SD mg/dL	CV %
CSF	Low	6.30	0.07	1.0	0.11	1.8
CSF	Mid	26.5	0.4	1.6	0.6	2.4
CSF	High	35.0	0.7	1.9	0.9	2.5
Urine	Low	1.68	0.02	0.9	0.07	4.3
Urine	Mid	3.28	0.02	0.6	0.08	2.5
Urine	High	20.0	0.3	1.4	0.4	2.1

b. Analytical Range (Linearity)

Analytical range (linearity) studies were designed to meet the requirements of CLSI guidelines EP06-A *"Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline"*. All testing was carried out using an AU5800 analyzer.

High and low albumin pools were prepared to achieve albumin concentrations spanning the required linear range. The high pool was prepared by spiking pools with HSA. The high urine and CSF pools were diluted with urine and CSF respectively to generate the lower concentrations required for the 11 point linearity panel.

The studies were performed on 11 linearity concentration levels. Each dilution was assayed in quadruplicate and the mean analytical results were plotted versus the relative analyte concentration.

A polynomial regression analysis was performed on the data and the bias of the polynomial from the 1st order curve was evaluated.

This study demonstrates acceptable linearity for the claimed measuring ranges.

Sample Type	Measuring Range (mg/dL)
Urine	0.7 - 45
CSF	1 - 45

c. Traceability and Value Assignment

The Urine/CSF Albumin calibrator values are traceable to the International Federation of Clinical Chemistry Certified Reference Material ERM®- DA470k.

The calibrator was standardized to the reference standard ERM®- DA470k. The assignment was carried out by determining multiple calibration curves using multiple dilutions of DA470k.

The assignment of the master calibrator from the international standard was carried out using an AU2700 analyzer and the values were confirmed and performance tested on an AU640 and AU2700 analyzer.

The assignment of other calibrator lots from the master calibrator was carried out using an AU680 analyzer and the values were confirmed and performance tested on an AU400 and AU680 analyzer.

d. Reagent and Calibrator Stability

Shelf-Life

Accelerated stability testing was carried out following CLSI guideline EP25-A "*Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline";* with the aim to establish initial claims of 18 months for both reagent and calibrator. The testing followed the guidelines for a packaging design change to an existing product with established stability claims. All testing was carried out using an AU5800 analyzer. Testing was performed at multiple elevated temperatures using three reagent lots and three calibrator lots and demonstrated that the reagent and calibrator are stable for 18 months at 2 - 8°C.

Reagent On-Board, Calibration Frequency and Calibrator Open Vial Stability

On-Board (OB) stability, calibration frequency, and calibrator open vial stability testing was carried out following CLSI guideline EP25-A "*Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline".* All testing was carried out using an AU5800 analyzer.

Testing was performed using three reagent lots and three calibrator lots. Calibration was performed on the first day. At each time point Urine & CSF control material was run in duplicate. The maximum time point exceeded the claim. For the reagent, linearity was assessed after the final time point.

A 60 day reagent on-board claim, a 60-day calibration frequency claim, and a 30-day calibrator open vial stability claim was established.

e. Sensitivity (Detection Limits)

LoB (Limit of Blank), LoD (Limit of Detection) and LoQ (Limit of Quantitation) studies were designed from CLSI guideline EP17-A2 "*Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures Approved Guideline - Second Edition*". All testing was carried out using an AU5800 analyzer.

Correctly operating AU Systems should exhibit sensitivity less than or equal to 0.7 mg/dL for Urine and less than or equal to 1.0 mg/dL for CSF. LoB was calculated as the upper 95th percent confidence interval of a result from an analyte free sample. Where the calculated LoB is < 0, this was rounded to 0. LoD is defined as the lowest albumin concentration that can be detected with a probability of 95 %. LoQ is defined as the lowest concentration with an inter-assay precision of < 20% CV.

<u>LoB and LoD</u>

The experimental design consisted of replicate measurements on blank and low level samples using three lots of reagent across multiple days. A total of 60 blank replicates per reagent lot and 60 low level sample replicates per reagent lot were generated. This was comprised of 4 blank samples and 4 low levels samples for urine and CSF, run 5-fold for 3 days. Four separate saline pools were used as blanks

to determine LoB, and four concentrations of 0.1, 0.2, 0.35 and 0.5 mg/dL prepared by dilution of a quantified urine and CSF pool with 0.9% saline were used for determining LoD.

LoQ

For LoQ, the experimental design utilized functional sensitivity to establish the claim. Six pools with concentrations of approximately 0.1, 0.2, 0.35, 0.5, 0.7 and 1 mg/dL albumin in urine and CSF were used. For each pool, samples were measured in duplicate, twice daily, over the course of 20 working days (n=80). A minimum of a 2 hour interval was left between the two runs.

The LoQ sensitivity claim met acceptance criteria of ≤ 0.7 mg/dL for urine and ≤ 1.0 mg/dL for CSF.

Sample Type	LoB (mg/dL)	LoD (mg/dL)	LoQ (mg/dL)
Urine	0.00	0.07	0.70
CSF	0.00	0.13	0.70

f. Interferences (Analytical Specificity)

Interference studies were designed based on CLSI Guideline EP07-A2: *"Interference Testing in Clinical Chemistry; Approved Guideline - Second Edition"* and used to assess common or known substances which could interfere with the Urine/CSF Albumin Assay. All testing was carried out using an AU5800 analyzer.

The interfering substances analyzed were tested at two Urine/CSF Albumin concentrations, approximately 1.5 - 3 mg/dL and 10 - 20 mg/dL for the Urine application, and 10 - 20 mg/dL and 25 - 35 mg/dL for the CSF application. Urine pools were prepared by spiking pooled human urine samples with purified human serum albumin to achieve the required concentrations. CSF pools were prepared by diluting pooled human CSF samples with 0.9% saline to achieve the required concentrations. The sample pools tested were at ≥ 5 different levels of interferent to determine the magnitude of the effect. Each interferent concentration was tested in quadruplicate. The data analysis involved calculating the difference in recovery of the samples with and without the potential interfering substances. A summary of the sample pools and results are detailed in the table below.

Note: No significant interference (NSI) is defined as ≤ ± 10% or ± 0.2 mg/dL.

Potential Interfering Substance	Interference Pool Details	Interferent Level (mg/dL)
URINE		
Calcium	Urine pools spiked with stock calcium chloride solution	NSI up to 78 mg/dL
Creatinine	Urine pools spiked with stock creatinine solution	NSI up to 300 mg/dL
Glucose	Urine pools spiked with stock glucose solution	NSI up to 3000 mg/dL
Urea	Urine pools spiked with stock urea solution	NSI up to 5000 mg/dL
Ascorbic Acid	Urine pools spiked with stock ascorbic acid solution	NSI up to 500 mg/dL

Potential Interfering Substance	Interference Pool Details	Interferent Level (mg/dL)
Citrate	Urine pools spiked with stock sodium citrate solution	NSI up to 50 mg/dL
Magnesium	Urine pools spiked with stock magnesium chloride solution	NSI up to 400mg/dL
Oxalate	Urine pools spiked with stock sodium oxalate Solution	NSI up to 30 mg/dL
Conjugated Bilirubin	Urine pools spiked with stock conjugated bilirubin solution	NSI up to 40 mg/dL
Hemoglobin	Urine pools spiked with stock hemoglobin solution	NSI up to 500 mg/dL
Acetone	Urine pools spiked with stock acetone solution	NSI up to 350 mg/dL
Uric Acid	Urine pools spiked with stock uric acid solution	NSI up to 10 mg/dL
Urobilinogen	Urine pools spiked with stock urobilinogen solution	NSI up to 2.25 mg/dL
Acetaminophen	Urine pools spiked with stock acetaminophen solution	NSI up to 300 mg/dL
Ibuprofen	Urine pools spiked with stock ibuprofen solution	NSI up to 400 mg/dL
Metronidazole	Urine pools spiked with stock metronidazole solution	NSI up to 600 mg/dL
5-aminosalicylic acid	Urine pools spiked with stock 5-aminosalicylic acid solution	NSI up to 150 mg/dL
CSF		
Hemoglobin	CSF pools spiked with stock hemoglobin solution	NSI up to 500 mg/dL
Conjugated Bilirubin	CSF pools spiked with stock conjugated bilirubin solution	NSI up to 40 mg/dL

g. Prozone

All testing was carried out using an AU5800 analyzer. Human urine and CSF were spiked with human serum to create a prozone high pool of ≥ 2000 mg/dL. The albumin concentration of the high prozone pools were determined using 3 replicates of at least 3 dilutions in the measuring range. Urine or 0.9% saline was used to prepare a series of dilutions of the high pool. Prozone panels were run n = 3. All samples from the upper end of the linear range up to the claimed prozone tolerance generated a flagged result that indicated a result above the linear range.

Performance Characteristics - Comparison Studies

a. Method Comparison

Method comparison and bias estimation experiments were designed using CLSI Guideline EP09-A3 *"Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline"*.

Urine Application

Patient urine samples were run to compare this Urine Albumin assay on the AU5800 analyzer against another commercially available assay. Results of Deming regression analysis were as follows:

Slope = 1.09	Intercept = 0.03 mg/dL	r = 1.0	n = 131	Sample range = (0.81 - 40.7 mg/dL)

CSF Application

Patient CSF samples were run to compare this CSF Albumin assay on the AU5800 analyzer against another commercially available assay. Results of Deming regression analysis were as follows:

Slope = 1.05	Intercept = -0.77 mg/dL	r = 0.99	n = 131	Sample range = 1.72 - 41.2 mg/dL

b. Expected Values/Reference Interval

Reference Intervals were taken from the literature.

Expected values/Reference range for Urine Albumin excretion:

Matrix		24-hr collection (mg/24 h)	Timed collection (µg/min)	Spot Collection (µg/mg creatinine)
Urine[1]	Normal	<30	<20	<30
	Moderately Increased	30-299	20-199	30-299
	Clinical Albuminuria	≥300	≥200	≥300

Expected values/Reference range for CSF Albumin:

CSF[2]: 3 mo - 4y 0 - 45 mg/dL
> 4 y 10 - 30 mg/dL

1. American Diabetes Association. Diabetic Nephropathy. Diabetes Care 25:(Suppl. 1):S85-S89.
2. Painter PC, Cope JY, Smith JL. Reference information for the clinical laboratory. In: Burtis CA, Ashwood ER, eds. Tietz textbook of clinical chemistry, Philadelphia: WB Saunders Company, 1999; 1800pp.

Urine Application:
CLSI guideline EP28-A3c *"Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline - Third Edition"* was used as a guideline to validate this reference interval using 20 urine samples.

c. Clinical Studies
Not applicable

d. Clinical Cut-off
Not applicable

9.0 Conclusion

The conclusions drawn from the non-clinical testing (discussed above) demonstrate that the Urine/CSF Albumin and Urine/CSF Albumin Calibrator is as safe, as effective, and performs as well as the predicate devices. The submitted information in this pre-market notification is complete and supports a substantial equivalence decision.