March 14, 2019

Ortho-Clinical Diagnostics, Inc.
Darlene Phillips
Manager, Regulatory Affairs
100 Indigo Creek Drive
Rochester, NY 14626

Re: K190326
Trade/Device Name: VITROS XT Chemistry Products UREA-CREA Slides
Regulation Number: 21 CFR 862.1770
Regulation Name: Urea nitrogen test system
Regulatory Class: Class II
Product Code: CDN, JFY
Dated: February 15, 2019
Received: February 19, 2019

Dear Darlene Phillips:

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. 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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190326

Device Name
VITROS XT Chemistry Products UREA-CREA Slides

Indications for Use *(Describe)*
For in vitro diagnostic use only
The UREA test within the VITROS XT Chemistry Products UREA-CREA Slides quantitatively measures urea concentration, reported either as urea nitrogen or as urea (UREA), in serum, plasma, and urine using the VITROS XT 7600 Integrated System. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases

The CREA test within the VITROS XT Chemistry Products UREA-CREA Slides quantitatively measures creatinine (CREA) concentration in serum, plasma, and urine using the VITROS XT 7600 Integrated System. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Special conditions for use statement: For prescription 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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is**:** k190326

Submitter's Information
Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-4253
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Contact Person:
Darlene J Phillips, RAC
Manager, Regulatory Affairs

Date of Preparation: February 12, 2019

Device Proprietary Name(s):
VITROS XT Chemistry Products UREA-CREA Slides

Common Names:
Urea nitrogen assay
Creatinine assay

Classification Names

Test	Product Code	Class	Regulation Section	Panel
UREA	CDN	Class II	21 CFR 862. 1770 Urea nitrogen test system	Clinical Chemistry (75)
CREA	JFY	Class II	21 CFR 862. 1225 Creatinine test system	

Predicate Device(s)

Predicate Devices	FDA 510(k) Number
VITROS Chemistry Products BUN/UREA Slides	k001885
VITROS Chemistry Products CREA Slides	k182063

Intended Use Statement(s)

VITROS XT Chemistry Products UREA-CREA Slides

Rx Only For in vitro diagnostic use only

The UREA test within the VITROS XT Chemistry Products UREA-CREA Slides quantitatively measures urea concentration, reported either as urea nitrogen or as urea (UREA), in serum, plasma, and urine using VITROS XT 7600 Integrated Systems. Measurements obtained by this device are used in the diagnosis and treatment of certain renal and metabolic diseases.

The CREA test within the VITROS XT Chemistry Products UREA-CREA Slides quantitatively measures creatinine (CREA) concentration in serum, plasma, and urine using VITROS XT 7600 Integrated Systems. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

Device Description

The new device, the VITROS XT Chemistry Products UREA-CREA Slide is a single device that contains both a UREA test and a CREA test multilayered, analytical element coated on a polyester support separated by a plastic barrier sealed within a single slide frame. In this format, individual reactions occur and test results are generated for each analyte independently of the other analyte.

To perform the UREA test, a drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. Water and nonproteinaceous components then travel to the underlying reagent layer, where the urease reaction generates ammonia. The semipermeable membrane allows only ammonia to pass through to the color-forming layer, where it reacts with the indicator to form a dye. The reflection density of the dye is measured and is proportional to the concentration of urea in the sample.

To perform the CREA test, a drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. Creatinine diffuses to the reagent layer, where it is hydrolyzed to creatine in the rate-determining step. The creatine is converted to sarcosine and urea by creatine amidinohydrolase. The sarcosine, in the presence of sarcosine oxidase, is oxidized to glycine, formaldehyde, and hydrogen peroxide. The final reaction involves the peroxidase-catalyzed oxidation of a leuco dye to produce a colored product. Following addition of the sample, the slide is incubated. During the initial reaction phase, endogenous creatine in the sample is oxidized. The resulting change in reflection density is measured at 2 time points. The difference in reflection density is proportional to the concentration of creatinine present in the sample.

Comparison to Predicate Devices

The following tables show similarities and differences between the new and predicate devices.

Summary of the technological characteristics of the device compared to the predicate device		
Device Characteristic	**New Device VITROS XT UREA-CREA Slide (New)**	**Predícate Devices VITROS BUN/UREA Slide [k001885] VITROS CREA Slide [k182063] (Current)**
Intended Use	Same for each individual test For *in vitro* diagnostic use only. The UREA test within the VITROS XT Chemistry Products UREA-CREA Slides quantitatively measures urea concentration, reported either as urea nitrogen or as urea (UREA), in serum, plasma, and urine. The CREA test within the VITROS XT Chemistry Products UREA-CREA Slides quantitatively measures creatinine (CREA) concentration in serum, plasma, and urine.	For *in vitro* diagnostic use only. VITROS Chemistry Products BUN/UREA Slides quantitatively measure urea concentration, reported either as urea nitrogen (BUN) or as urea (UREA), in serum, plasma, and urine. VITROS Chemistry Products CREA Slides quantitatively measure creatinine (CREA) concentration in serum, plasma, and urine
Device Description	No Change	Multilayered, analytical element coated on a polyester support
Basic Principle	No Change	BUN/UREA Colorimetric CREA Colorimetric Two point rate
Incubation time and temperature	No Change	Approximately 5 minutes 37°C (98.6° F)
Sample type	No Change	Serum, plasma, and urine

Summary of the technological characteristics of the device compared to the predicate device		
Device Characteristic	**New Device VITROS XT UREA-CREA Slide (New)**	**Predícate Devices VITROS BUN/UREA Slide [k001885] VITROS CREA Slide [k182063] (Current)**
Amount of Slide Reactive Ingredients per cm^2 (test)	The composition of the analytical element of each test within the VITROS XT Slide will remain the same as that used in each predicate device	BUN/UREA Urease (jack bean) 1.2 U and N-propyl-4-(2,6-dinitro-4-chlorobenzyl)-quinolonium ethane sulfonate (ammonia indicator) 0.26 mg. CREA Creatinine amidohydrolase (Flavobacterium sp.,) 0.20 U; creatine amidinohydrolase (Alcaligenes sp.) 3.6 U; sarcosine oxidase (Bacillus sp.) 0.55 U; peroxidase (horseradish root) 1.6 U and 2-(3,5-dimethoxy-4-hydroxyphenyl)-4,5-bis(4-dimethylaminophenyl) imidazole (leuco dye) 32 µg.
Assay Range	No Change	BUN/UREA (mg/dL urea N) Serum/plasma 2.0–120.0 Urine 67–2520 CREA (mg/dL) Serum/plasma 0.15–14.0 Urine 3.2–346.5
Calibrators	Same	VITROS Chemistry Products Calibrator Kit 1
Controls	Same	VITROS Chemistry Products Performance Verifier I and II
Differences		
Instrumentation	VITROS XT 7600 Integrated System	VITROS 250/350, 5,1 FS and 4600 Chemistry Systems VITROS 5600 and XT 7600 Integrated Systems
Sample volume	UREA 4.3 µL CREA 3.2 µL	BUN/UREA 5.5 µL CREA 6 µL

Non-Clinical Testing Analytical Performance

Method Comparison

Method Comparison testing followed CLSI Protocol EP09-A3, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples. S*erum and urine samples were evaluated on the VITROS XT Chemistry Products UREA-CREA Slides using the VITROS XT 7600 Integrated System and on VITROS Chemistry Products BUN/UREA Slides and VITROS Chemistry Products CREA Slides using the VITROS 5600 Integrated System. The correlation between the predicate and the new tests within the VITROS XT UREA-CREA Slides on the VITROS XT 7600 Integrated System is summarized below.

Summary of Method Comparison Weighted Deming Regression Analysis Data
Units mg/dL

Test	N	Slope	Intercept	Corr. Coeff.	Test Range	Measuring range
UREA Serum	124	1.04	0.00	0.999	3 - 106	2.0 – 120.0
UREA Urine	128	1.05	-13.21	0.999	105 - 2451	67 – 2520
CREA Serum	130	1.00	-0.01	1.000	0.20 - 13.49	0.15 – 14.0
CREA Urine	116	1.01	-0.93	0.998	13.0 – 336.6	3.2 – 346.5

Precision

Precision was evaluated with patient pools and quality control materials following CLSI Protocol EP05-A3, *Evaluation of Precision Performance of Quantitative Methods; Approved Guideline—Third Edition*, using the VITROS XT Chemistry Products UREA-CREA Slides on the VITROS XT 7600 Integrated System. The test included a minimum of 80 observations (2 replicates per run, 2 runs per day over 20 days) for serum and urine. The long term precision analysis is summarized below.

The data presented are a representation of test performance and are provided as a guideline. Variables such as sample handling and storage, reagent handling and storage, laboratory environment, and system maintenance can affect reproducibility of test results.

Repeatability (formerly called within-run precision) was determined using two replicates per run. Within Day precision was determined using two runs per day with two replications per run. Within Lab precision was determined using a single lot of slides and a single calibration.

UREA nitrogen Serum									**Units (mg/dL urea N)**
Fluid Id	**Mean Conc.**	**Repeatability**		**Within Day**		**Within Lab**		**No. of Obs.**	**No. of Days**
		SD	**CV%**	**SD**	**CV%**	**SD**	**CV%**		
Pool 1	3	0.1	4.0	0.2	8.0	0.2	8.7	80	20
Pool 2	10	0.1	1.0	0.2	1.8	0.2	2.1	80	20
Native Pool	11	0.1	1.2	0.2	2.1	0.2	2.1	80	20
Control 1	17	0.3	1.6	0.3	1.9	0.3	1.9	80	20
Control 2	51	0.7	1.3	0.7	1.3	0.8	1.5	80	20
Pool 3	107	1.1	1.0	1.2	1.2	1.4	1.3	80	20

UREA nitrogen Urine									Units (mg/dL urea N)
Fluid Id	Mean Conc.	Repeatability		Within Day		Within Lab		No. of Obs.	No. of Days
		SD	CV%	SD	CV%	SD	CV %		
Pool 1	84	2.4	2.8	6.0	7.1	7.2	8.5	80	20
Native Pool	293	3.8	1.3	5.4	1.8	6.8	2.3	80	20
Control 1	404	4.1	1.0	7.1	1.8	9.1	2.3	80	20
Control 2	683	7.6	1.1	7.6	1.1	12.2	1.8	80	20
Pool 2	1453	14.0	1.0	19.5	1.3	19.5	1.3	80	20
Pool 3	2331	21.4	0.9	28.2	1.2	30.6	1.3	80	20

CREA Serum									Units (mg/dL)
Fluid Id	Mean Conc.	Repeatability		Within Day		Within Lab		No. of Obs.	No. of Days
		SD	CV%	SD	CV%	SD	CV%		
Pool 1	0.66	0.007	1.1	0.008	1.2	0.011	1.7	80	20
Control 1	0.85	0.010	1.2	0.012	1.4	0.014	1.6	80	20
Native Pool	0.86	0.012	1.4	0.012	1.4	0.014	1.6	80	20
Control 2	5.41	0.030	0.6	0.040	0.7	0.084	1.6	80	20
Pool 2	9.41	0.068	0.7	0.072	0.8	0.163	1.7	80	20
Pool 3	12.62	0.090	0.7	0.107	0.8	0.220	1.7	80	20

CREA Urine									Units (mg/dL)
	Mean Conc.	Repeatability		Within Day		Within Lab		No. of Obs.	No. of Days
		SD	CV%	SD	CV%	SD	CV%		
Native Pool	39.0	0.26	0.7	0.37	1.0	0.52	1.3	80	20
Control 1	58.5	0.67	1.1	0.90	1.5	1.14	2.0	80	20
Control 2	137.5	1.47	1.1	2.20	1.6	3.15	2.3	80	20
Pool 2	239.4	2.13	0.9	2.27	0.9	3.13	1.3	80	20
Pool 3	317.2	2.00	0.6	4.13	1.3	5.44	1.7	80	20

Detection Limits

Detection capability studies for the UREA and CREA tests within the VITROS XT UREA-CREA Slides were evaluated according to CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures.

The Limit of Quantitation (LoQ) for the UREA test within the VITROS XT UREA-CREA Slides is 2.0 mg/dL for serum/plasma and 67 mg/dL for urine. The total number of LoQ determinations was 72. The Total Error goal used to accept the LoQ was ≤ 1.2 mg/dL for serum and ≤ 21 mg/dL Urea N for urine.

The Limit of Quantitation (LoQ) for the CREA test within the VITROS XT UREA-CREA Slides is 0.15 mg/dL for serum/plasma and 3.2 mg/dL for urine. The total number of LoQ

determinations was 72 for serum and 64 for urine. The Total Error goal used to accept the LoQ was ≤ 0.06 mg/dL for serum and ≤ 1.2 mg/dL for urine.

The results of this analysis are summarized below:

	UREA (mg/dL urea N)		**CREA (mg/dL)**	
	Serum	**Urine**	**Serum**	**Urine**
LOB	1.5	23	0.05	1.1
LOD	1.7	27	0.07	1.3
LOQ	1.7	41	0.11	2.3
Claimed LOQ	2.0	67	0.15	3.2

Linearity

Linearity studies were performed according to CLSI EP06-A, *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach Approved Guideline (2003).* VITROS XT UREA-CREA Slides were tested on the VITROS XT 7600 Integrated System. A series of twenty proportionally related admixtures of low and high test fluids were tested with to verify linearity of the UREA and CREA serum and urine tests; each sample was tested in quadruplicate. The linearity studies support the claimed measuring ranges for the individual tests within the VITROS XT UREA-CREA Slides.

Assay	**Fluid**	**Measuring Range (mg/dL)**	**Linear Range (mg/dL)**
UREA nitrogen	Serum/plasma	2.0– 120.0	1.93 – 148.79
	Urine*	67 - 2520	62.46 – 3198.85
CREA	Serum/plasma	0.15 - 14.0	0.04 – 14.86
	Urine*	3.2 – 346.5	1.1 – 418.3

* After multiplying by 21x dilution factor

Serum and plasma samples with values greater than the measuring range may be diluted up to a maximum dilution of 1 part sample with 1 part diluent. A 7% BSA solution was found to be an acceptable diluent for serum and plasma specimens assayed using VITROS XT Chemistry Products UREA-CREA Slides.

Urine samples with values greater than the measuring range may be diluted up to a maximum dilution of 1 part sample with 1 part diluent. Isotonic saline and reagent-grade water were both found to be acceptable diluents for UREA urine specimens assayed using the VITROS XT Chemistry Products UREA-CREA Slides. Reagent-grade water was found to be an acceptable diluent for CREA urine specimens assayed using the VITROS XT Chemistry Products UREA-CREA Slides.

Expected Values

The expected values of the UREA and CREA tests within the VITROS XT UREA-CREA Slides are the not changed from those of the predicate assays. Each laboratory should confirm the validity of these intervals for the population it serves.

UREA Reference Interval

The serum reference interval is the central 95% of results from an internal study of 3160 apparently healthy adults from a working population (612 females and 2548 males).

The urine reference interval is based on an external study.

UREA Reference Interval	
Serum	
Male	9-20 mg/dL urea N
Female	7-17 mg/dL urea N
Urine	
24-hour	12-20 g urea N /day*

* Urea nitrogen concentration (mg/dL) x 24-hour volume (dL) = mg/day.

CREA Reference Interval

The serum reference intervals are the central 95% of results from an external study of apparently healthy adults (serum: 180 males and 180 females).

The urine reference intervals are based on a separate external study.

CREA Reference Interval	
Serum	
Male	0.66–1.25 mg/dL
Female	0.52–1.04 mg/dL
Urine	
Male	1000–2000 mg/day*
Female	800–1800 mg/day*

* Creatinine concentration (mg/dL) x 24-hour volume (dL) = mg/day.

Specificity

The UREA and CREA tests within the VITROS XT Chemistry Products UREA-CREA Slide were screened for interfering substances following CLSI document EP07-A3, Interference Testing in Clinical Chemistry. The supplemental tables in CLSI document EP37 were referenced for recommended testing concentrations for analytes and endogenous substances that may interfere in clinical chemistry measurement procedures.

Point estimates of the effects of potential interferents on VITROS XT UREA-CREA Slides were made using the paired difference method. Dose-response analysis was conducted to characterize the degree of interference for each substance, and expected bias was reported at the lowest test level which did not meet acceptance criteria for bias as shown in the product claims.

Known Interferences

Ammonium ions may cause an increase in measured UREA value equivalent to the specimen’s nitrogen content.

Serum and Plasma

The substances listed in the table, when tested at the concentrations indicated, caused the bias shown. The bias is an estimate of the maximum bias observed.

It is possible that other interfering substances may be encountered. These results are representative; however, your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

UREA Test

Interferent	Interferent Concentration	Urea nitrogen Concentration	Bias
Total protein	12 g/dL	37 mg/dL	-4.3 mg/dL

Ninety-six (96) test substances, when tested at the concentrations indicated, as well as serum pH at 6.8 and 8.8, were found not to interfere, bias < 2.0 mg/dL at 9 mg/dL urea N and bias < 4.0 mg/dL at 40 mg/dL urea N, with the UREA test within VITROS XT UREA-CREA Slides in serum.

CREA Test

- Creatine: At a creatinine concentration of 1.5 mg/dL (133 µmol/L), creatine greater than 8 mg/dL (707 µmol/L) will be flagged with a DP code (because highly elevated creatine concentrations may cause excessive background density). For unflagged samples, residual bias because of creatine will be less than 0.15 mg/dL (13 µmol/L). At a creatinine concentration of 14 mg/dL (1237 µmol/L), creatine greater than 1 mg/dL (88 µmol/L) will be flagged with a DP code. Residual bias for unflagged samples will be less than 2%. Refer to "Sample Dilution" for dilution instructions.
- Proline: Patients receiving hyperalimentation fluids containing proline may show an increase of 0.2 mg/dL (18 µmol/L). Do not collect specimens from intravenous fluid lines contaminated with hyperalimentation fluid.

Interferent	Interferent Concentration	Creatinine Concentration	Bias
	Conv. Units	Conv. Units (mg/dL)	Conv. Units (mg/dL)
Bilirubin, conjugated	58 mg/dL	1.6	-0.16
Dipyrone (Metamizole)*	9 mg/dL	1.6	-0.20
	14 mg/dL	4.9	-0.73
Ethamsylate	4.1 mg/dL	1.7	-0.18
Glutathione	69 mg/dL	1.6	-0.23
N-Ethyl glycine**	0.40 mg/dL	1.7	0.21
Proline	18 mg/dL	1.7	0.24
Tolazamide	5.0 mg/dL	1.6	-0.24
		4.6	-0.55
Total protein	15 g/dL	1.7	0.26
	12 g/dL	5.0	0.53

* Dipyrone at 9 mg/dL is equivalent to 6X the equivalent of a 1000 mg oral dose, or 1.5X the equivalent of a 1000 mg intravenous dose.

** N-ethyl glycine is a metabolite of lidocaine and may be present at high levels in patients on long-term lidocaine therapy.

Eighty-eight (88) test substances, when tested at the concentrations indicated, as well as serum pH at 6.8 and 8.8, were found not to interfere, bias < 0.13 mg/dL at 1.5 mg/dL and bias < 0.44 mg/dL at 5 mg/dL, with the CREA test within VITROS XT UREA-CREA Slides in serum.

Urine

UREA Test

Two (2) substances were found to interfere with the UREA test in VITROS XT UREA-CREA Slides in urine. Both of these substances are urine preservatives containing boric acid, and the use of urine specimens preserved with boric acid is not recommended for use in the UREA test within VITROS XT UREA-CREA Slides.

Nineteen (19) test substances were found not to interfere with the UREA test in urine, bias < 90 mg/dL at 900 mg/dL urea N and bias < 140 mg/dL at 1400 mg/dL urea N.

CREA Test

Twenty-three (23) test substances were found not to interfere, bias < 5.8 mg/dL at 60 mg/dL and bias < 17 mg/dL at 200 mg/dL, with the CREA test in urine.

Other Limitations

Certain drugs and clinical conditions are known to alter urea nitrogen and creatinine concentrations *in vivo.* For additional information, refer to one of the published summaries.

Conclusion

The conclusions drawn from the nonclinical tests (discussed above) demonstrate the VITROS XT Chemistry Products UREA-CREA Slides for use on the VITROS XT 7600 Integrated System are as safe, effective, and perform as well as the predicate devices. The information submitted in the premarket notification is complete and supports a substantial equivalence decision.