July 8, 2022

bioMérieux SA
Julien Thao My
Regulatory Affairs Specialist
376 Chemin de l'Orme
Marcy l'Etoile, 69280
France

Re: K210793
Trade/Device Name: VIDAS® NEPHROCHECK®
Regulation Number: 21 CFR 862.1220
Regulation Name: Acute Kidney Injury Test System
Regulatory Class: Class II
Product Code: PIG
Dated: March 3, 2022
Received: March 7, 2022

Dear Julien Thao My:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiologial Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210793

Device Name
VIDAS® NEPHROCHECK®

Indications for Use *(Describe)*
VIDAS® NEPHROCHECK® is an automated test for use on the VIDAS® 3 instrument for the immunoenzymatic quantitative determination of TIMP-2 (Tissue Inhibitor of Metalloproteinase-2) and IGFBP-7 (Insulin-like Growth Factor-Binding Protein 7) proteins in human urine using the ELFA technique (Enzyme Linked Fluorescent Assay) for calculation of the AKIRISK™ Score.
The VIDAS® NEPHROCHECK® assay is intended to be used in conjunction with clinical evaluation in patients who currently have or have had within the past 24 hours acute cardiovascular and or respiratory compromise and are ICU patients as an aid in the risk assessment for moderate or severe acute kidney injury (AKI) within 12 hours of patient assessment. The VIDAS® NEPHROCHECK® test is intended to be used in patients 21 years of age or older.

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 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirement of Safe Medical Devices Act of 1990 and 21 CFR 807.92.

K210793 - VIDAS® NEPHROCHECK®

A. Submitter Information

Submitter's Name:	bioMérieux SA
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Contact Person:	Julien THAO MY
Phone Number:	+33 4 78 87 70 64
Fax Number:	+33 4 78 87 76 65
Date of Preparation:	15 March 2021

B. Device Name

Trade Name:	VIDAS® NEPHROCHECK®
Common Name	VIDAS NEPH
Classification Name:	Acute Kidney Injury test system (21 CFR 862.1220, Product Code PIG) - Class 2 in vitro Diagnostic device

C. Predicate Device Name

Trade Name: NEPHROCHECK Test Kit, Astute Medical, Inc., K171482

D. Device Description

Each VIDAS® NEPHROCHECK® kit contains: x60 NEPH Reagent Strips, x60 NEPH Solid Phase Receptacles (SPR), 1 NEPH control and 1 NEPH calibrator.
The VIDAS® NEPHROCHECK® principle combines an enzyme immunoassay competition method with a final fluorescent detection (ELFA).

The Solid Phase Receptacle (SPR®) serves as the solid phase as well as the pipetting device for the assay. The interior of the NEPH SPR is coated with mouse monoclonal IgG anti-IGFBP-7 andanti-TIMP-2.

The Reagent Strips consist of 10 wells covered with a labeled foil seal. Well 1 is designated for the sample. Six of the wells contain conjugate, wash buffers and substrate. Last well contains the fluorescence substrate.
All of the assay steps are performed automatically by the instrument.
Two detection steps, one for each protein, are performed successively in Well 10.
• The first step is a classical detection step with measurement of the substrate background and incubation of the substrate in the bottom of the SPR®, to generate the first fluorescent signal, which is specific for the IGFBP-7 protein.
• Before the second detection step, the antibodies and proteins in the bottom of the SPR® are removed using the cleaning solution contained in Well 5. The previously used substrate in Well 10 is removed and replaced by fresh substrate contained in Well 9. A new substrate background is then measured, and the substrate is incubated in the top of the SPR® to generate the second fluorescent signal, which is specific for the TIMP-2 protein.

For each protein, the intensity of the fluorescence is proportional to its concentration in the sample. At the end of the test, the protein concentrations are calculated by the instrument in relation to the two calibration curves, one corresponding to each protein, and encoded in the MLE data.
The instrument calculates the AKIRISK™ Score, which is defined as the product of the concentrations of the two proteins, expressed in ng/mL, divided by 1000:
AKIRISK™ Score = ([TIMP-2] x [IGFBP-7]) / 1000
The result of the VIDAS® NEPHROCHECK® assay is reported as the AKIRISK™ Score.

E. Intended Use
VIDAS® NEPHROCHECK® is an automated test for use on the VIDAS® 3 instrument for the immunoenzymatic quantitative determination of TIMP-2 (Tissue Inhibitor of Metalloproteinase-2) and IGFBP-7 (Insulin-like Growth Factor-Binding Protein 7) proteins in human urine using the ELFA technique (Enzyme Linked Fluorescent Assay) for calculation of the AKIRISK™ Score.
The VIDAS® NEPHROCHECK® assay is intended to be used in conjunction with clinical evaluation in patients who currently have or have had within the past 24 hours acute cardiovascular and or respiratory compromise and are ICU patients as an aid in the risk assessment for moderate or severe acute kidney injury (AKI) within 12 hours of patient assessment. The VIDAS® NEPHROCHECK® test is intended to be used in patients 21 years of age or older.

F. Technological Characteristics Summary

A general comparison of the similarities and differences of the assays with the predicate is presented in the table below**.**

Item	VIDAS® NEPHROCHECK® assay	Astute Medical NEPHROCHECK Test Kit
Intended Use	VIDAS® NEPHROCHECK® is an automated test for use on the VIDAS® 3 instrument for the immunoenzymatic quantitative determination of TIMP-2 (Tissue Inhibitor of Metalloproteinase-2) and IGFBP-7 (Insulin-like Growth Factor-Binding Protein 7) proteins in human urine using the ELFA technique (Enzyme Linked Fluorescent Assay). The VIDAS® NEPHROCHECK® assay is intended to be used in conjunction with clinical evaluation in patients who currently have or have had within the past 24 hours acute cardiovascular and or respiratory compromise and are ICU patients as an aid in the risk assessment for moderate or severe acute kidney injury (AKI) within 12 hours of patient assessment. The VIDAS® NEPHROCHECK® test is intended to be used in patients 21 years of age or older.	The Astute Medical NEPHROCHECK Test System is intended to be used in conjunction with clinical evaluation in patients who currently have or have had within the past 24 hours acute cardiovascular and or respiratory compromise and are ICU patients as an aid in the risk assessment for moderate or severe acute kidney injury (AKI) within 12 hours of patient assessment. The NEPHROCHECK® Test System is intended to be used in patients 21 years of age or older.
Specimen	Urine	Urine
Analyte	TIMP-2 IGFBP-7	TIMP-2 IGFBP-7
Automated	Yes	Yes
Assay Technique	Enzyme-linked fluorescent assay (ELFA)	Lateral flow with fluorescent detection
Assay principle	Labeled antibody competition method	Same

G. Nonclinical Testing

A summary of the performance results is presented below.

Analytical specificity

The study was performed as recommended by CLSI® document EP7-Ed3 *"Interference Testing in Clinical Chemistry, 3rd Edition"*.

The study has been carried out on different lots of VIDAS® NEPHROCHECK® assay tested on the VIDAS® 3 instrument.

Interferences:

The measurement procedure for VIDAS® NEPHROCHECK® was found not to interfere from any of the potentially interfering substances except with Phosphate up to 1100 mg/L, with Albumin up to 6900 mg/L and with Hemoglobin up to the concentration of 60 mg/L.

Cross-reactivity of structurally related molecules:

All of the potentially cross-reactant substances tested were found not to interfere with the measurement of VIDAS® NEPHROCHECK® assay.

Detection and quantitation limits

The study was performed as recommended by CLSI® document EP17-A2 *"Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures, 2nd Edition"*.

The claimed Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) for the VIDAS® NEPHROCHECK® assay on the VIDAS 3 instrument :

	AKIRISK™ SCORE
LoB	0.002
LoD	0.003
LoQ	0.003

The study supports the following requirement:

- LoB < LoD ≤ LoQ ≤ 0.04 for AKIRISK™ Score,

with an associated accuracy goal for the LoQ defined as 20% total within-lot precision, which is satisfactory for the intended clinical use.

Analytical Measuring Interval

The VIDAS® NEPHROCHECK® analytical measuring intervals are defined as follows:

- [0.04-10.00] for AKIRISK™ Score.

Linearity

The study was performed as recommended by CLSI® document EP6-A *"Evaluation of Linearity of Quantitative Measurement Procedures"*.
The study was conducted on the VIDAS 3 instrument.

Metrological traceability, product Calibrator S1 and product Control C1

The study was performed as recommended by CLSI® document EP09-A3c *"Measurement Procedure Comparison and Bias Estimation Using Patient Samples, 3rd Edition"*.
The values with the VIDAS® NEPHROCHECK® assay were assigned to be traceable to the predicate device Astute NEPHROCHECK® assay, an IVD-labeled commercial product.

Sample stability

Fresh Urine:

Fresh urine samples can be stored for 5 hours at 18-25°C in open tube, either in LBP-treated tube, or in plastic tube with no additive without any impact on the results of the VIDAS® NEPHROCHECK® assay.
Fresh urine samples can be stored for 24 hours at 2-8°C in closed LBP-treated tube, without any impact on the results of the VIDAS® NEPHROCHECK® assay.
Fresh urine samples cannot be stored for 24 hours at 2-8°C in hemolysis tube.

Centrifugation of fresh urine can be performed at either 2-8°C or room temperature without any impact on the results of the VIDAS® NEPHROCHECK® assay.

Frozen Urine:

Frozen urine samples can be stored for 6 months at ≤-60°C, including two freeze-thaw cycles, without any impact on the results of the VIDAS® NEPHROCHECK® assay.

H. Clinical Testing

Precision

The study was performed as recommended by CLSI® document EP5-A3 *"Evaluation of Precision of Quantitative Measurement Procedures, 3rd Edition"*.

The precision estimates of the AKIRISK™ Score are as follows:

- Within-run precision: from 3.9% to 5.7%,
- Between-day Within-site precision: from 4.9% to 6.8%,
- Between-site/instrument/lot precision: from 5.6% to 10.2%

Reference interval

The study was performed as recommended by CLSI® document EP28-A3 "*Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition*".

The overall reference interval for apparently healthy subjects was <0.04 to 2.50 and for subjects with stable chronic morbidities was <0.04 to 2.66. The reference intervals were comparable for apparently healthy subjects and subjects with stable chronic morbidities, and for males and females from the two cohorts. The distribution of the AKIRISK™ Scores of these subjects without AKI were put in regards to those of the intended use patients with AKI.

Diagnostic Accuracy

The study was performed as recommended by CLSI® document EP12-A2 guideline '*User Protocol for Evaluation of Qualitative Test Performance; Approved guideline – Second edition'*.

The accuracy performance characteristics obtained for the VIDAS® NEPHROCHECK® assay at the cut-off value of 0.30 were the following:

- For the Topaz cohort (Study A):
  - The sensitivity observed was 89.9%,
  - The specificity observed was 45.2%.
- For the Opal cohort (Study B):
  - The sensitivity observed was 82.8%,
  - The specificity observed was 40.2%.

The clinical performance of the VIDAS® NEPHROCHECK® assay demonstrates that the assay is substantially equivalent to the predicate device as an aid in the risk assessment of moderate or severe AKI within 12 hours of patient assessment in adult patients who currently have or have had within the past 24 hours acute cardiovascular and or respiratory compromise and are ICU patients.

I. Conclusion

The results from the non-clinical and clinical studies submitted in this premarket notification are complete and demonstrate that the VIDAS® NEPHROCHECK® assay is substantially equivalent to the predicate device.