



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

September 5, 2014

ASTUTE MEDICAL, INC.  
C/O KARIN A. HUGHES, Ph.D., VP CLINICAL AND REGULATORY STRATEGY  
3550 GENERAL ATOMICS CT.  
BUILDING 2, R 636  
SAN DIEGO, CA 92121

Re: DEN130031  
NEPHROCHECK® Test System  
Evaluation of Automatic Class III Designation – *De Novo* Request  
Regulation Number: 21 CFR 862.1220  
Regulation Name: Acute kidney injury test system.  
Regulatory Classification: Class II  
Product Code: PIG  
Dated: June 05, 2013  
Received: June 05, 2013

Dear Dr. Hughes:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your *de novo* request for classification of the NEPHROCHECK® Test System, which is a prescription device. The intended use of the NEPHROCHECK® Test System is

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.

FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the NEPHROCHECK® Test System, and substantially equivalent devices of this generic type, into class II under the generic name, “Acute kidney injury test system”.

FDA identifies this generic type of device as: Acute kidney injury test system. An acute kidney injury test system is intended to measure one or more analytes in human samples as an aid in the assessment of a patient’s risk for developing acute kidney injury. Test results are

intended to be used in conjunction with other clinical and diagnostic findings, consistent with professional standards of practice, including confirmation by alternative methods.

Section 513(f)(2) of the FD&C Act was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for *de novo* classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device type.

On June 05, 2013, FDA received your *de novo* request for classification of the NEPHROCHECK® Test System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the NEPHROCHECK® Test System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the *de novo* request, FDA has determined that the NEPHROCHECK® Test System intended for use as follows

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.

can be classified in class II with the establishment of special controls for this type of device. FDA believes that class II special controls identified later in this order, along with the applicable general controls, provide reasonable assurance of the safety and effectiveness of the device type.

Table – Identified Risks and Required Mitigations

<b>Identified Risks</b>	<b>Required Mitigations</b>
Incorrect interpretation of test results	Special controls (1) (2), and (3)
Incorrect test results	Special control (3)

In combination with the general controls of the FD&C Act, the acute kidney injury test system is subject to the following special controls:

- 1) Premarket notification submissions must detail an appropriate end user device training program that will be offered while marketing the device as part of your efforts to mitigate the risk of incorrect interpretation of test results.
- 2) As part of the risk management activities performed as part of your 21 CFR 820.30 design controls, you must document the appropriate end user device training program provided in your premarket notification submission to satisfy special control (1) that will be offered while marketing the device as part of your efforts to mitigate the risk of incorrect interpretation of test results.
- 3) Robust clinical data demonstrating the positive predictive value, negative predictive value, sensitivity and specificity of the test in the intended use population must be submitted as part of the premarket notification submission.

In addition, this is a prescription device. Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the acute kidney injury test system they intend to market prior to marketing the device and receive clearance to market from FDA.

Please be advised that FDA's decision to grant this *de novo* request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the *de novo* request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Amy Ghering at 301-796-1656.

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